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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 37, 40, 70, 71, 72, 73, 76, and 95

[NRC–2018–0183]

RIN 3150–AK14

Miscellaneous Corrections—Organizational Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to make miscellaneous corrections. These changes include removing an office from a list of office recipients, removing an office reference, correcting an office designation and a phone number, removing and correcting division titles, and removing a followup reporting instruction. This document is necessary to inform the public of these non-substantive amendments to the NRC's regulations.

DATES: This final rule is effective on December 21, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0183 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0183. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents Collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jill Shepherd-Vladimir, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1230, email: *Jill.Shepherd-Vladimir@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is amending its regulations in parts 37, 40, 70, 71, 72, 73, 76, and 95 of title 10 of the *Code of Federal Regulations* (10 CFR) to make miscellaneous corrections. These changes include removing an office from a list of office recipients, removing an office reference, correcting an office designation and a phone number, removing and correcting division titles, and removing a followup reporting instruction. This document is necessary to inform the public of these non-substantive amendments to the NRC's regulations.

II. Summary of Changes

10 CFR Part 37

Remove Office Reference. In § 37.7(a), this final rule removes the Director, Division of Security Policy, Office of Nuclear Security and Incident Response, from the list of recipients.

10 CFR Parts 37 and 40

Remove Reporting Instruction. In §§ 37.81(g) and 40.64(c)(2) and (3), this final rule removes the erroneous instructions for where to submit a copy of a followup notification. These paragraphs already point to the sections that provide the appropriate mailing address and addressee(s).

10 CFR Parts 37, 40, 70, 71, 72, and 73

Remove Division Title. In §§ 37.77, 40.23(b)(1), 40.66(a) and (b)(5), 40.67(a), 70.5, 70.20, 71.97, 73.4, 73.37, 73.71, 73.72, 73.73, and 73.74, this final rule removes the Division of Security Policy to ensure that correspondence goes directly to the Director, Office of Nuclear Security and Incident Response rather than to a division director.

10 CFR Parts 40, 73, and 76

Correct Division Title. In §§ 40.23(c), 40.66(c), and 40.67(c) and (d), 73.26, 73.27, 73.67, and 76.5a, this final rule corrects the title of the Division of Security Policy to read as Division of Physical and Cyber Security Policy.

10 CFR Part 40

Correct Designation. In § 40.23(b)(2)(ix), this final rule replaces the Division of Security Policy with the higher level designation of the Office of Nuclear Security and Incident Response.

Correct Telephone Number. In § 40.23(d), this final rule removes the incorrect telephone number ''(301) 415–6828'' and replaces it with the correct telephone number ''(301) 287–3598'' for the Director of the Division of Physical and Cyber Security Policy.

10 CFR Part 70

Correct Office Designation. In § 70.32(c)(2), (e), and (i), this final rule replaces the Office of Nuclear Security and Incident Response with the Office of Nuclear Material Safety and Safeguards.

10 CFR Part 72

Remove Division Title. In § 72.186(b), this final rule removes the Division of Spent Fuel Management so that notifications go to the Director, Office of Nuclear Material Safety and Safeguards rather than to division level management.

10 CFR Part 95

Remove Division Title. In § 95.9(a), this final rule removes the Division of Security Operations so that notification go to Office level management rather than division level management.

III. Rulemaking Procedure

Under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the requirements for publication in the **Federal Register** of a notice of proposed rulemaking and opportunity for comment if it finds, for good cause, that it is impracticable, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), the NRC finds good cause to waive notice and opportunity for comment on these

amendments, because notice and opportunity for comment is unnecessary. The amendments will have no substantive impact and are of a minor and administrative nature dealing with corrections to certain CFR sections or are related only to management, organization, procedure, and practice. These changes include removing an office from a list of office recipients, removing an office reference, correcting an office designation and a phone number, removing and correcting division titles, and removing a followup reporting instruction. The Commission is exercising its authority under 5 U.S.C. 553(b) to publish these amendments as a final rule. The amendments are effective December 21, 2018. These amendments do not require action by any person or entity regulated by the NRC, and do not change the substantive responsibilities of any person or entity regulated by the NRC.

IV. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in 10 CFR 51.22(c)(2), which categorically excludes from environmental review rules that are corrective or of a minor, nonpolicy nature and do not substantially modify existing regulations. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this rule.

V. Paperwork Reduction Act

This final rule does not contain a collection of information as defined in the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

VI. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

VII. Backfitting and Issue Finality

The NRC has determined that the corrections in this final rule do not constitute backfitting and are not inconsistent with any of the issue finality provisions in 10 CFR part 52. The amendments are non-substantive in nature, including removing an office from a list of office recipients, removing an office reference, correcting an office designation and a phone number, removing and correcting division titles, and removing a followup reporting instruction. They impose no new requirements and make no substantive changes to the regulations. The corrections do not involve any provisions that would impose backfits as defined in 10 CFR chapter I, or would be inconsistent with the issue finality provisions in 10 CFR part 52. For these reasons, the issuance of the rule in final form would not constitute backfitting or represent a violation of any of the issue finality provisions in 10 CFR part 52. Therefore, the NRC has not prepared any additional documentation for this correction rulemaking addressing backfitting or issue finality.

VIII. Congressional Review Act

This final rule is not a rule as defined in the Congressional Review Act (5 U.S.C. 801–808).

List of Subjects

10 CFR Part 37

Byproduct material, Criminal penalties, Exports, Hazardous materials transportation, Imports, Licensed material, Nuclear materials, Penalties, Radioactive materials, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Incorporation by reference, Intergovernmental relations, Nuclear materials, Packaging and containers, Penalties, Radioactive materials, Reporting and recordkeeping requirements.

10 CFR Part 72

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

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Incorporation by reference, Imports, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 76

Certification, Criminal penalties, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Special nuclear material, Uranium, Uranium enrichment by gaseous diffusion.

10 CFR Part 95

Classified information, Criminal penalties, Penalties, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 37, 40, 70, 71, 72, 73, 76, and 95:

PART 37—PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

■ 1. The authority citation for part 37 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 81, 103, 104, 147, 148, 149, 161, 182, 183, 223, 234, 274 (42 U.S.C. 2014, 2073, 2111, 2133, 2134, 2167, 2168, 2169, 2201, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

■ 2. Revise § 37.7(a) to read as follows:

§ 37.7 Communications.

* * * * *

(a) By mail addressed to: ATTN: Document Control Desk; Director, Office of Nuclear Reactor Regulation; Director, Office of New Reactors; or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, U.S. Nuclear

Regulatory Commission, Washington, DC 20555–0001;

* * * * *

§ 37.77 [Amended]

■ 3. In § 37.77, wherever it appears, remove the title ''Division of Security Policy,'' and in paragraph (c)(1), remove the phrase ''of Nuclear Security''.

§ 37.81 [Amended]

■ 4. In § 37.81(g) introductory text, remove the third sentence.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

■ 5. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

§ 40.23 [Amended]

■ 6. Amend § 40.23 as follows:
■ a. In paragraph (b)(1), remove the title ''Division of Security Policy,'';
■ b. In paragraph (b)(2)(ix), remove the title ''Division of Security Policy'' and add in its place the title ''Office of Nuclear Security and Incident Response''.
■ c. In paragraph (c), remove the title ''Division of Security Policy'' and add in its place the title ''Division of Physical and Cyber Security Policy''.
■ d. In paragraph (d), remove the title ''Division of Security Policy'' and add in its place the title ''Division of Physical and Cyber Security Policy''; and remove the telephone number ''(301) 415–6828'' and add in its place the telephone number ''301–287–3598''.

§ 40.64 [Amended]

■ 7. In § 40.64(c)(2) and (3), remove the last sentence in each paragraph.

§ 40.66 [Amended]

■ 8. Amend § 40.66 as follows:
■ a. In paragraph (a), remove the title ''Division of Security Policy,'';
■ b. In paragraph (b)(5), remove the title ''Division of Security Policy,'' and add in its place the title ''Director,''; and
■ c. In paragraph (c), remove the title ''Division of Security Policy,'' and add in its place the title ''Director,''.

§ 40.67 [Amended]

■ 9. Amend § 40.67 as follows:
■ a. In paragraph (a), remove the title ''Division of Security Policy,''; and
■ b. In paragraphs (c) and (d), remove the title ''Division of Security Policy'' and add in its place the phrase ''Director, Office of Nuclear Security and Incident Response''.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

■ 10. The authority citation for part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§§ 70.5 and 70.20b [Amended]

■ 11. In §§ 70.5 and 70.20b, wherever it appears, remove the title ''Division of Security Policy,''.

§ 70.32 [Amended]

■ 12. In § 70.32, wherever it appears, remove the title ''Division of Security Policy, Office of Nuclear Security and Incident Response'' and add in its place the title ''Office of Nuclear Material Safety and Safeguards''.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

■ 13. The authority citation for part 71 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 180 (42 U.S.C. 10175); 44 U.S.C. 3504 note. Section 71.97 also issued under Sec. 301, Public Law 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

§ 71.97 [Amended]

■ 14. In § 71.97, wherever it appears, remove the title ''Division of Security Policy,''.

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

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

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

§ 72.186 [Amended]

■ 16. In § 72.186(b), remove the title ''Division of Spent Fuel Management,''.

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

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

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note. Section 73.37(b)(2) also issued under Sec. 301, Public Law 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

§§ 73.4, 73.37, 73.71, 73.72, 73.73 and 73.74 [Amended]

■ 18. In §§ 73.4, 73.37, 73.71, 73.72, 73.73, and 73.74, wherever it appears, remove the title ''Division of Security Policy,''.

§§ 73.26, 73.27, and 73.67 [Amended]

■ 19. In §§ 73.26, 73.27, and 73.67, wherever it appears, remove the title ''Division of Security Policy'' and add in its place the title ''Division of Physical and Cyber Security Policy''.

PART 76—CERTIFICATION OF GASEOUS DIFFUSION PLANTS

■ 20. The authority citation for part 76 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 122, 161, 193(f), 223, 234, 1701 (42 U.S.C. 2152, 2201, 2243(f), 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206, 211 (42 U.S.C. 5841, 5846, 5851); 44 U.S.C. 3504 note.

§ 76.5 [Amended]

■ 21. In § 76.5(a), remove the title ''Division of Security Policy,''.

PART 95—FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

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

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, as amended, 25 FR 1583, 3 CFR, 1959–1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298.

§ 95.9 [Amended]

■ 23. In § 95.9(a), remove the title ''Division of Security Operations,''.

Dated at Rockville, Maryland, this 16th day of November 2018.

For the Nuclear Regulatory Commission.

Pamela J. Shepherd-Vladimir,

Acting Chief, Regulatory Analysis and Rulemaking Support Branch, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–25378 Filed 11–20–18; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL RESERVE SYSTEM

12 CFR Parts 211 and 238

[Docket No. R–1569]

RIN 7100–AE82

Large Financial Institution Rating System; Regulations K and LL

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Final rule.

SUMMARY: The Board is adopting a new rating system for large financial institutions in order to align with the Federal Reserve's current supervisory programs and practices for these firms. The final rating system applies to bank holding companies and non-insurance, non-commercial savings and loan holding companies with total consolidated assets of $100 billion or more, and U.S. intermediate holding companies of foreign banking organizations established under Regulation YY with total consolidated assets of $50 billion or more. The rating system will assign component ratings for capital planning and positions, liquidity risk management and positions, and governance and controls, and introduces a new rating scale. The Federal Reserve will assign initial ratings under the new rating system in 2019 for bank holding companies and U.S. intermediate holding companies subject to the Large Institution Supervision Coordinating Committee framework and in 2020 for all other large financial institutions. The Board is revising provisions in Regulations K and LL so they will remain consistent with certain features of the new rating system.

DATES: The final rule is effective on February 1, 2019.

FOR FURTHER INFORMATION CONTACT: Richard Naylor, Associate Director, (202) 728–5854, Molly Mahar, Associate Director, (202) 973–7360, Vaishali Sack, Assistant Director, (202) 452–5221, Christine Graham, Manager, (202) 452–3005, Division of Supervision and Regulation; Laurie Schaffer, Associate General Counsel, (202) 452–2272, Benjamin W. McDonough, Assistant General Counsel, (202) 452–2036, Scott Tkacz, Senior Counsel, (202) 452–2744, Keisha Patrick, Senior Counsel, (202) 452–3559, or Christopher Callanan, Counsel, (202) 452–3594, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869.

SUPPLEMENTARY INFORMATION:

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I. Background

The Board is adopting a new supervisory ratings framework for certain large financial institutions that is designed to:

- Align with the Federal Reserve's current supervisory programs and practices;
- Enhance the clarity and consistency of supervisory assessments and communications of supervisory findings and implications; and
- Provide transparency related to the supervisory consequences of a given rating.

The final ratings framework applies to bank holding companies and non-insurance, non-commercial savings and loan holding companies with total consolidated assets of $100 billion or more, and U.S. intermediate holding companies of foreign banking organizations established under Regulation YY with total consolidated assets of $50 billion or more.

In the years following the 2007–2009 financial crisis, the Federal Reserve developed a supervisory program specifically designed to enhance resiliency and address the risks posed by large financial institutions to U.S. financial stability (LFI supervisory program). As set forth in SR letter 12–17/CA letter 12–14, the LFI supervisory program focuses supervisory attention on the core areas that are most likely to threaten the firm's financial and operational strength and resilience (capital, liquidity, and governance and controls).[1] This orientation is intended to reduce the likelihood of the failure or material distress of a large financial institution, and reduce the risk to U.S. financial stability in the event of failure.

The Federal Reserve coordinates its supervision of firms that pose the greatest risk to U.S. financial stability through the Large Institution Supervision Coordinating Committee (LISCC). The LISCC supervisory program conducts annual horizontal reviews of LISCC firms and firm-specific examination work focused on evaluating those firms' (i) capital adequacy under normal and stressed conditions; (ii) liquidity positions and risk management practices; (iii) recovery and resolution preparedness; and (iv) governance and controls.[2] For large financial institutions that are not LISCC firms, the Federal

[1] ''Financial strength and resilience'' is defined as maintaining effective capital and liquidity governance and planning processes, and sufficiency of related positions, to provide for continuity of the consolidated organization (including its critical operations and banking offices) through a range of conditions.

''Operational strength and resilience'' is defined as maintaining effective governance and controls to provide for continuity of the consolidated organization (including its critical operations and banking offices) and to promote compliance with laws and regulations, including those related to consumer protection, through a range of conditions.

Under SR letter 12–17/CA letter 12–14, ''banking offices'' are defined as U.S. depository institution subsidiaries and the U.S. branches and agencies of foreign banking organizations.

[2] See the list of firms included in the LISCC supervisory program at *https://www.federalreserve.gov/bankinforeg/large-institution-supervision.htm.*

Reserve performs horizontal reviews and firm-specific supervisory work focused on capital, liquidity, and governance and control practices, which are tailored to reflect the risk characteristics of these institutions.

Since 2004, the Federal Reserve has used the ''RFI/C(D)'' rating system (referred to as the ''RFI rating system'') to communicate its supervisory assessment of every bank holding company regardless of its asset size, complexity, or systemic importance.[3] The RFI rating system is focused on the risk management practices (R component) and financial condition (F component) of the consolidated organization, and includes an assessment of the potential impact (I component) of a bank holding company's nondepository entities on its subsidiary depository institution(s).

The Federal Reserve has not modified the RFI rating system to reflect the substantial changes to the statutory and regulatory framework relating to large financial institutions, or the Federal Reserve's implementation of the LFI supervisory program in recent years. In light of these changes, the Board is adopting a new rating system applicable to these firms that is more closely aligned with the LFI supervisory program, so that the ratings more directly communicate the results of the Federal Reserve's supervisory assessment.

Because the statutory, regulatory, and supervisory framework for community and regional bank holding companies has not undergone material changes since the financial crisis, the RFI rating system remains a relevant and effective tool for developing and communicating supervisory assessments for those firms. Therefore, the RFI rating system will continue to be used in the supervision of these organizations.

II. Notice of Proposed Rulemaking and Overview of Comments

On August 17, 2017, the Board invited public comment on a notice of proposed rulemaking to adopt a new rating system for large financial institutions (proposed LFI rating system).[4] The proposed LFI rating system would have applied to bank holding companies and non-insurance, non-commercial savings and loan holding companies with total consolidated assets of $50 billion or more, and U.S. intermediate holding companies (U.S. IHCs) of foreign banking organizations established under Regulation YY.[5]

Under the proposed LFI rating system, each banking organization would have been assigned ratings for three separate components: Capital Planning and Positions; Liquidity Risk Management and Positions; and Governance and Controls. The ratings would have been assigned using a four-point non-numeric scale (Satisfactory/Satisfactory Watch, Deficient-1, and Deficient-2).[6] A firm would need a ''Satisfactory'' or ''Satisfactory Watch'' rating for each of the three component ratings to be considered ''well managed'' for various purposes under the Board's rules and federal law. The proposal would not have included the assignment of a standalone composite rating or any subcomponent ratings. In addition, the proposal would have amended certain provisions of the Board's existing regulations (Regulation K and Regulation LL) to make them compatible with the proposed rating scale.

The Board received 16 comments on the proposal from supervised firms, trade associations, industry consultants, and individuals. In addition, Federal Reserve staff held several meetings on the proposal with members of the public and obtained supplementary information from certain commenters. Summaries of these meetings are available on the Board's public website.

Most commenters generally supported the proposal to develop a new rating system that would be aligned with the Federal Reserve's LFI supervisory program. However, many commenters also expressed concerns regarding specific aspects of the proposal, including the applicability and implementation of the proposed LFI rating system and its underlying components, the lack of a standalone composite rating, the ratings scale, and the consequences of ratings assigned under the rating system.

Separately, the Board invited comment on two other proposals closely related to the proposed LFI rating system. The first proposal addressed proposed guidance on supervisory expectations for boards of directors, which set forth attributes of an effective board of directors of LFIs,[7] and the second proposal addressed an LFI's management of business lines and independent risk management and controls.[8] The Board continues to consider comments on these proposals, and thus, is not adopting either proposal at this time.

III. Overview of Final Rule and Modifications From the Proposal

The final rating system adopts the core elements of the proposed LFI rating system, with certain modifications to address commenter concerns. Consistent with the proposal, a banking organization will be assigned three component ratings: Capital Planning and Positions; Liquidity Risk Management and Positions; and Governance and Controls. In addition, although the final LFI rating system retains a four-category, non-numeric rating scale, it identifies the top two categories as ''Broadly Meets Expectations'' and Conditionally Meets Expectations'' to align with the definitions of those categories.

IV. Final LFI Rating System

A. Applicability

In the proposal, the LFI rating system would have applied to bank holding companies, non-insurance, non-commercial savings and loan holding companies, and U.S. IHCs of foreign banking organizations with $50 billion or more in total consolidated assets. The Board received several comments regarding the applicability of the LFI rating system. For example, one commenter suggested that the Board should use risk-based factors instead of asset size to determine which firms are subject to the LFI rating system. Another commenter suggested that the $50 billion threshold should be raised.

In addition to the comments received, the Board has taken into consideration that since the proposal, section 401 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA) amended section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) to modify the $50 billion minimum asset threshold for general application of enhanced prudential standards.[9] Effective immediately on the date of its enactment, bank holding companies with total consolidated assets equal to or greater than $50 billion and less than

[3] *See* SR letter 04–18, ''Bank Holding Company Rating System,'' 69 FR 70444 (December 6, 2004), at *https://www.federalreserve.gov/boarddocs/srletters/2004/sr0418.htm.*

The Federal Reserve adopted to apply the RFI rating system on a fully implemented basis to all savings and loan holding companies (SLHCs) with total consolidated assets of less than $100 billion, excluding SLHCs engaged in significant insurance or commercial activities. *See* 83 FR 56081 (November 9, 2018). The Federal Reserve had applied the RFI rating system to SLHCs on an indicative basis since assuming supervisory responsibility for those firms from the Office of Thrift Supervision in 2011.

[4] 82 FR 39049 (August 17, 2017).

[5] 12 CFR 252.153.

[6] In the proposed LFI rating system, Satisfactory Watch was a subcategory of ''Satisfactory.''

[7] 82 FR 37219 (August 9, 2017).

[8] 83 FR 1351 (January 11, 2018).

[9] Public Law 115–174, section 401, 132 Stat. 1296 (2018).

$100 billion were no longer subject to these standards.[10]

In consideration of the comments received and the statutory changes under EGRRCPA, the final LFI rating system is being adopted for bank holding companies and, non-insurance and non-commercial savings and loan holding companies with total consolidated assets of $100 billion or more, and for U.S. IHCs of foreign banking organizations established under Regulation YY with total consolidated assets of $50 billion or more.[11] The decision to increase the asset threshold to $100 billion for bank holding companies and non-insurance, non-commercial SLHCs is consistent with the minimum threshold for enhanced prudential standards established by EGRRCPA as well as the Board's intention to tailor certain of its regulations for domestic firms to implement EGRRCPA.[12] The Board has retained the asset threshold of $50 billion for U.S. IHCs of foreign banking organizations as it continues to consider appropriate tailoring of its regulations for FBOs in light of EGRRCPA; however, the Board may adjust this asset threshold in the future if necessary.

Bank holding companies with total consolidated assets of at least $50 billion but less than $100 billion will continue to be evaluated subject to the RFI rating system. The Board is currently reviewing existing supervisory guidance with respect to these firms to determine whether it is appropriate to make revisions to further distinguish supervisory expectations for firms with total consolidated assets of less than $100 billion.

The proposed LFI rating system would not have applied to SLHCs that are predominantly engaged in insurance or commercial activities. The Board continues to consider the appropriate regulatory regime for these firms. As such, the Board will continue to rate these SLHCs on an indicative basis under the RFI rating system as it considers further the appropriate manner to assign supervisory ratings to such firms on a permanent basis.[13]

B. Timing and Implementation

Under the proposal, the initial set of LFI ratings would have been assigned starting in 2018. Several commenters provided views regarding the timing and implementation of the final LFI rating system. For instance, commenters suggested that Federal Reserve delay implementation of the LFI rating system for firms with assets of less than $250 billion until the completion of regulatory reforms. Other commenters requested that the Board coordinate the implementation of the final LFI rating system with the related guidance setting forth attributes of effective boards and expectations for the management of business lines and independent risk management and controls, and the Federal Reserve provide more clarity regarding the implementation of the guidance.[14] Another commenter requested that the Federal Reserve run a pilot program before implementing the final LFI rating system.

In light of the changes to the application of enhanced prudential standards under EGRRCPA, the Board is currently considering ways to tailor the regulatory and supervisory framework for firms that are not in the LISCC portfolio. Accordingly, in order to conduct that review and seek public comment on any proposed revisions to the Board's regulations, the Federal Reserve will continue to use the RFI rating system for ratings in 2019 for holding companies with assets of $100 billion or more and U.S. intermediate holding companies of foreign banking organizations that are not subject to the LISCC framework. The Federal Reserve will assign ratings using the final LFI rating system beginning in early 2020.[15]

For bank holding companies and U.S. IHCs of foreign banking organizations subject to the LISCC framework, the Federal Reserve will begin assigning ratings using the final LFI rating system in early 2019. In early 2019, LISCC firms will receive all three component ratings under the LFI rating system; following the initial rating assignment, updates to individual rating components may be assigned and communicated to the firm on a rolling basis, but at least annually.

The Board believes that it is important to have the LFI rating system become effective soon in order to align the supervisory rating system with the Board's current consolidated supervisory framework for large financial institutions. This alignment will enhance the clarity of the Board's supervisory program, as both the Board's supervisory assessment of a firm and its related assignment of the firm's ratings will directly relate with the three core areas of focus in the consolidated supervisory framework: Capital, liquidity, and governance and controls. For example, supervisory assessments of a firm's capital and liquidity can be prominently reflected in the ratings assigned under the LFI rating system, whereas such assessments are less easily communicated within the structure of the RFI rating system. To ensure that ratings are assigned in a consistent and fair manner, the Federal Reserve is implementing staff training and will undertake a multi-level review and vetting before ratings are assigned.

As noted above, the Board invited comment on two sets of guidance that

[10] Section 401(f) of EGRRCPA also provides that any bank holding company, regardless of asset size, that has been identified as a Global Systemically Important Bank (GSIB) under the Board's GSIB capital surcharge rule shall be considered a bank holding company with $250 billion or more in total consolidated assets for purposes of applying the standards under section 165 and certain other provisions. EGRRCPA section 401.

The Board issued two statements—one individually, and the other jointly with the FDIC and OCC—that provided information on Board-administered regulations and associated reporting requirements that EGRRCPA immediately affected. *See* Board and Interagency statements regarding the impact of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), July 6, 2018, available at *https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20180706a1.pdf; https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20180706b1.pdf.* The statements describe interim positions that the Board and other agencies have taken until the agencies finalize amendments to their regulations to implement EGRRCPA.

[11] For a bank holding company and savings and loan holding company, total consolidated assets of $100 billion or more will be calculated based on the average of the firm's total consolidated assets in the four most recent quarters as reported on the firm's quarterly financial reports filed with the Federal Reserve. A firm will continue to be rated under the final LFI rating system until it has less than $95 billion in total consolidated assets, based on the average total consolidated assets as reported on the firm's four most recent quarterly financial reports filed with the Federal Reserve. As noted in the proposal, the Federal Reserve may determine to apply the RFI rating system or another applicable rating system in certain limited circumstances.

SLHCs are considered to be engaged in significant commercial activities if they derive 50 percent or more of their total consolidated assets or total revenues from activities that are not financial in nature under section 4(k) of the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1843(k)). SLHCs are considered to be engaged in significant insurance underwriting activities if they are either insurance companies or hold 25 percent or more of their total consolidated assets in subsidiaries that are insurance companies. SLHCs that meet these criteria are excluded from the definition of ''covered savings and loan holding company'' in § 217.2 of the Board's Regulation Q. *See* 12 CFR 217.2.

[12] *See* 83 FR 56081 (November 9, 2018).

[13] Concurrent with the issuance of this final LFI rating system, the Board adopted the RFI rating system for SLHCs that are depository in nature. *See supra* fn. 3. The RFI rating system will cease to apply to SLHCs with $100 billion or more in total consolidated assets upon the effective date of LFI rating system for such firms. The Board also continues to consider the appropriate regulatory regime for systemically important nonbank financial companies designated by the Financial Stability Oversight Council (FSOC) for supervision by the Federal Reserve.

[14] Comments related to implementation of the LFI rating system for FBOs are discussed below.

[15] In early 2020, banking organizations that are not LISCC firms will receive all three component ratings under the LFI rating system; following the initial rating assignment, updates to individual rating components may be assigned and communicated to the firm on a rolling basis, but at least annually.

related to the governance and controls component rating—the first established principles regarding effective boards of directors focused on the performance of a board's core responsibilities, and the second set forth core principles of effective senior management, the management of business lines, and independent risk management and controls for large financial institutions. The Board continues to consider comments on both proposals, and thus, is not adopting either set of guidance at this time. Given that the guidance establishing principles regarding effective boards of directors is not finalized, the Federal Reserve intends to rely primarily on principles set forth in SR letter 12–17/CA letter 12–14 and safety and soundness to assess the effectiveness of a firm's board of directors. Given that the management of business lines and independent risk management and controls guidance is not finalized, the Federal Reserve will rely on existing risk management guidance to assess the effectiveness of a firm's management of business lines and independent risk management and controls.[16]

Reliance on other regulators

Commenters requested that the Federal Reserve rely to a greater extent on the supervisory evaluations conducted by other regulators, including both domestic and foreign supervisors. Coordination with other domestic regulators and foreign supervisory authorities is a critical component of the LFI supervisory program. Federal Reserve staff meets regularly with counterparts at domestic and foreign regulatory agencies that have primary supervisory responsibility with respect to a banking organization or its subsidiaries, or its foreign bank parent, in order to leverage work and ensure effective coordination. In assigning LFI component ratings under the final LFI rating system, the Federal Reserve will continue to rely to the fullest extent possible on applicable information and assessments developed by other relevant supervisors and functional regulators.

Application to U.S. IHCs

The proposed LFI rating system would have applied to U.S. IHCs of foreign banking organizations. Some commenters requested that the Board delay application of the LFI rating system to U.S. IHCs until the Board sought comment on governance and controls guidance designed specifically for U.S. IHCs. Commenters requested clarification on how the assignment of LFI ratings to U.S. IHCs would interact with other ratings assigned to the U.S. operations of foreign banking organizations (the combined U.S. operations assessment) and the ROCA rating for U.S. branches and agencies.

Under the principle of national treatment, the Federal Reserve generally applies standards to the U.S. operations of a foreign banking organization consistent with those that apply to similarly situated U.S. banking organizations. The U.S. operations of a foreign banking organization are subject to regulatory standards set forth in Regulation YY, and expectations related to capital planning and positions, liquidity risk management and positions, and governance and controls, that are parallel to those that apply to a U.S. bank holding company. Applying the final LFI rating system to U.S. IHCs of foreign banking organizations would be consistent with national treatment and the Board's approach to regulating and supervising foreign banking organizations.

As commenters note, the Board did not apply the guidance setting forth attributes of effective boards to U.S. IHCs, in recognition of the fact that a U.S. IHC is a subsidiary of a foreign banking organization. U.S. IHCs will not be subject to examinations solely focused on effectiveness of the U.S. IHC's board of directors.[17] Rather, the Federal Reserve will indirectly assess the effectiveness of a U.S. IHC's board by considering whether weaknesses or deficiencies that are identified within the organization while conducting other supervisory work may be evidence of, or resulting from, governance-related oversight deficiencies. For example, governance-related oversight deficiencies could be noted in the context of a significant risk management or control weakness that is identified during an examination of capital planning or business line management.

The Board will continue to evaluate the U.S. branches of foreign banks under the ROCA system, and assign a single component rating to the foreign banking organization's U.S. operations. As noted in the preamble to the proposal, the Board is considering adjustments to the ratings for U.S. branches and the U.S. operations to better align with the LFI framework.

Commenters also requested clarity in how the LFI rating would impact the ''well managed'' status of a foreign banking organization that is a financial holding company. Under current law, a foreign banking organization that is a financial holding company must be well capitalized and must have a satisfactory composite rating of its U.S. branch and agency operations and a satisfactory rating of its U.S. combined operations, if one is given. As with the rating currently assigned to a U.S. IHC under the RFI system, the LFI rating assigned to the U.S. IHC would be an input into the rating of the combined U.S. operations of a foreign bank.

C. LFI Rating Components

Under the proposed LFI rating system, the Federal Reserve would have evaluated and assigned ratings for the following three components: Capital Planning and Positions; Liquidity Risk Management and Positions; and Governance and Controls. The final LFI rating system adopts these component categories as proposed.

Capital Planning and Positions

As proposed, the Capital Planning and Positions rating would have encompassed assessments of (i) the effectiveness of the governance and planning processes used by a firm to determine the amount of capital necessary to cover risks and exposures, and to support activities through a range of conditions; and (ii) the sufficiency of a firm's capital positions to comply with applicable regulatory requirements and to support the firm's ability to continue to serve as a financial intermediary through a range of conditions.

Several commenters sought clarification regarding the relationship between a firm's compliance with regulatory capital requirements and a firm's Capital Planning and Positions rating. In addition, some commenters asserted that receipt of a non-objection

[16] Existing risk management guidance includes, but is not limited to, SR letter 95–51, ''Rating the Adequacy of Risk Management Processes and Internal Controls at State Member Banks and Bank Holding Companies;'' SR letter 03–5, ''Amended Interagency Guidance on the Internal Audit Function and its Outsourcing;'' SR letter 12–17/CA letter 12–14, ''Consolidated Supervision Framework for Large Financial Institutions;'' SR letter 10–6, ''Interagency Policy Statement on Funding and Liquidity Risk Management,'' SR letter 13–1/CA letter 13–1, ''Supplemental Policy Statement on the Internal Audit Function and Its Outsourcing;'' SR letter 13–19/CA letter 13–21, ''Guidance on Managing Outsourcing Risk;'' SR letter 15–18, ''Supervisory Assessment of Capital Planning and Positions for LISCC Firms and Large and Complex Firms;'' and SR letter 15–19, ''Supervisory Assessment of Capital Planning and Positions for Large and Noncomplex Firms.'' In addition, Regulation YY sets forth risk management requirements, including liquidity risk management requirements.

[17] However, the Federal Reserve may consider the effectiveness of the IHC's board of directors in connection with other examinations. For example, the Federal Reserve may consider governance-related oversight deficiencies in the context of a significant risk management or control weakness that is identified during an examination of capital planning or business line management.

to a capital plan should result in (or create the presumption of) a firm receiving a ''Satisfactory'' rating for the Capital Planning and Positions component under the LFI rating system.

The final LFI rating system adopts the description of the Capital Planning and Positions component rating used in the proposal. A firm's capital rating under the LFI rating system will reflect a broad assessment of the firm's capital planning and positions, based on horizontal reviews and firm-specific supervisory work focused on capital planning and positions. In consolidating supervisory findings into a comprehensive assessment of a firm's capital planning and positions, the Federal Reserve will take into account the materiality of a firm's outstanding and newly identified supervisory issues.

A firm's compliance with minimum regulatory capital requirements will be considered in assigning the firm's Capital Planning and Positions component rating; however, the Federal Reserve may determine that a firm does not meet expectations regarding its capital position in light of its idiosyncratic activities and risks, even if the firm meets minimum regulatory capital requirements. Any findings from supervisory stress testing, such as CCAR or similar activities, will represent inputs into the Capital Planning and Positions component rating. However, with respect to any firm that may be subject to a qualitative review of its capital planning practices, there is no automatic link between the results of that review and the firm's capital rating.

Some commenters argued that the Board should discontinue its practice of publicly objecting or not-objecting to a firm's capital plan. Last year, the Board exempted firms with less than $250 billion in assets and less than $75 billion in nonbank assets from the CCAR qualitative assessment, and in the recent stress capital buffer proposal, the Board sought comments on potential changes to the CCAR qualitative assessment.[18] The Board is currently in the process of evaluating these comments.

In addition, commenters noted that the Board should clarify that the final LFI rating system does not create any new qualitative standards for capital planning, and others requested that the Board separately seek comment on the capital planning expectations included in SR letters 15–18 and 15–19. Consistent with the commenters' request, the Board confirms that the final LFI rating system does not create any new capital planning expectations applicable to LFIs. When the Board adopted SR letters 15–18 and 15–19, it did not seek comment on those letters, as they largely consolidated the Federal Reserve's existing capital planning guidance in one place. To the extent the Board considers adjustments to those letters in the future, the Board will take commenters' views into account.

Liquidity Risk Management and Positions

As proposed, the Liquidity Risk Management and Positions component rating would have encompassed assessments of (i) the effectiveness of a firm's governance and risk management processes used to determine the amount of liquidity necessary to cover risks and exposures, and to support activities through a range of conditions; and (ii) the sufficiency of a firm's liquidity positions to comply with applicable regulatory requirements and to support the firm's ongoing obligations through a range of conditions.

Several commenters requested that the Board clarify how the liquidity rating would be assigned and clarify the linkage between a firm's rating and its compliance with the minimum liquidity requirements. The final ratings system adopts the description of the Liquidity Risk Management and Positions component rating used in the proposal without change. In assessing the liquidity risk management and position of a banking organization, the Federal Reserve evaluates each firm's risk management practices by reviewing the processes that firms use to identify, measure, monitor, and manage liquidity risk and make funding decisions, and evaluating the firm's compliance with the liquidity risk management requirements of Regulation YY. The Federal Reserve evaluates a firm's liquidity positions against applicable regulatory requirements, and assesses the firm's ability to support its obligations through other means, such as its funding concentrations. A firm's liquidity rating will reflect the materiality of issues identified through the supervisory process.

In addition, commenters requested additional detail on the relationship between the Liquidity Risk Management and Positions rating of a LISCC firm and its performance in the Comprehensive Liquidity Assessment Review (CLAR). As for all component ratings, horizontal and firm-specific examination work conducted under the LISCC liquidity program, which is inclusive of the horizontal work covered under the CLAR, will represent a material input into a firm's liquidity rating. Unlike CCAR, the LISCC liquidity program's assessment does not result in an objection or non-objection ; rather, it results in supervisory findings communicated to the firm, which may include ''matters requiring attention'' and ''matters requiring immediate attention,'' as applicable.

Governance and Controls

The proposed Governance and Controls component rating would have evaluated the effectiveness of a firm's (i) board of directors,[19] (ii) management of business lines and independent risk management and controls,[20] and (iii) recovery planning (for domestic LISCC firms only).[21]

This component rating would have included consideration of a firm's compliance practices. One commenter suggested that the rating take into account only compliance matters that would have a material impact on a firm's financial and operational strength and resiliency. The Board expects all firms to comply fully with applicable laws and regulations, including those related to consumer protection. In assigning a supervisory rating, the Board will take into account the materiality of outstanding and identified supervisory issues, including the extent to which a matter would have a material impact on a firm's financial and operational strength and resiliency.

The proposed Governance and Controls component rating would have included a consideration of recovery planning for domestic LISCC firms, given the heightened risks that LISCC firms present to financial stability. One commenter suggested that the governance and controls rating not include recovery planning for domestic LISCC firms, because related supervisory expectations are already

[18] 83 FR 9308 (February 3, 2017); 83 FR 18160 (April 25, 2018).

[19] ''Board'' or ''board of directors'' also refers to the equivalent to a board of directors, as appropriate, as well as committees of the board of directors or the equivalent thereof, as appropriate.

[20] The final LFI rating system uses the term ''management of business lines'' instead of ''management of core business lines,'' in order to align with the proposed guidance on the management of business lines and independent risk management and controls.

[21] At this time, recovery planning expectations only apply to domestic bank holding companies subject to the Federal Reserve's LISCC supervisory framework. *See* SR letter 14–8, ''Consolidated Recovery Planning for Certain Large Domestic Bank Holding Companies.'' Should the Federal Reserve expand the scope of recovery planning expectations to encompass additional firms, this rating will reflect such expectations for the broader set of firms.

There are eight domestic firms in the LISCC portfolio: (1) Bank of America Corporation; (2) Bank of New York Mellon Corporation; (3) Citigroup, Inc.; (4) Goldman Sachs Group, Inc.; (5) JP Morgan Chase & Co.; (6) Morgan Stanley; (7) State Street Corporation; and (8) Wells Fargo & Company.

reflected in other aspects of the LFI rating system. The final LFI rating system maintains consideration of recovery planning in assessing the governance and controls of a LISCC firm, as effective recovery planning practices are central to ensuring that a LISCC firm has sufficient financial and operational strength to continue operations through a range of conditions.

The Board requested comment on whether resolution planning should also be a component of, or otherwise factored into, the LFI rating system. Several commenters argued against inclusion of resolution planning, stating, for example, that adding a separate component rating for resolution planning would be duplicative in light the current public deficiency findings under the resolution plan rule. One commenter supported the inclusion of resolution planning in the LFI rating system.

The Board has determined not to include a separate component rating for a firm's resolution planning as part of the final LFI rating system. The Board will continue to consider whether the LFI rating system should be modified in the future to include an assessment of the sufficiency of a firm's resolution planning efforts.

D. LFI Rating Scale

Under the proposed LFI rating system, ratings would have been assigned based on a four-point scale, with the following categories: *Satisfactory/Satisfactory Watch, Deficient-1, and Deficient-2*. One commenter expressed concern that the reduction in the number of ratings categories from five, as in the current RFI framework, to four, would result in the new rating framework being less flexible and nuanced, and lead to inadvertent rating downgrades.

A four-category rating scale is intended to increase the usability of the scale—under the RFI rating system, the highest rating of ''1'' and the lowest rating of ''5'' were rarely used when rating LFIs. Further, the ''Conditionally Meets Expectations'' rating category enables the Federal Reserve to identify certain material issues at a firm and provide a firm with notice and the ability to fix those issues before the firm experiences regulatory consequences as a result of the ratings downgrade.

The final LFI rating system adopts a similar four-category scale, but uses different terminology to improve the descriptiveness of the rating categories. Specifically, the final rating categories are: *Broadly Meets Expectations, Conditionally Meets Expectations, Deficient-1, and Deficient-2*. The final LFI rating system also clarifies the definitions within each category to provide additional guidance to examiners and provide transparency to firms about the calibration of each category.

Several commenters also expressed the need for the use of additional quantitative measures improve transparency and consistency in how ratings are derived. The Federal Reserve will continue to use quantitative measures, together with supervisory judgment, to inform a comprehensive assessment of a firm's Capital, Liquidity, and Governance and Controls.

Broadly Meets Expectations

In the proposal, the highest rating category was ''Satisfactory.'' A ''Satisfactory'' rating would have indicated that a firm is considered safe and sound and broadly meets supervisory expectations.

The final LFI rating system renames the rating category as ''Broadly Meets Expectations,'' to align more closely with the underlying definition of the rating category.[22] As with the proposal, the final ratings definition for ''Broadly Meets Expectations'' provides that a firm may have supervisory issues requiring corrective action; however, these issues are unlikely to present a threat to the firm's ability to maintain safe-and-sound operations through a range of conditions.

Two commenters suggested that the rating scale should include a higher rating above the ''Satisfactory'' designation, similar to the ''Strong'' rating utilized with the RFI, CAMELS, and other supervisory rating systems. The final LFI rating system does not include a ''Strong'' rating, which may suggest that the Federal Reserve expects firms to exceed, not simply meet, supervisory expectations. In addition, a ''Strong'' rating would not enhance or clarify supervisory communications, as a ''Strong'' rating would have no supervisory consequences.[23]

One commenter stated that the rule should clarify the circumstances under which MRAs or MRIAs would trigger a downgrade from the ''Satisfactory'' rating. As noted above, in consolidating supervisory findings into a comprehensive assessment in each category, the Board will take into account the materiality of a firm's outstanding and newly identified supervisory issues. While a given ratings assessment will depend on the circumstances, the LFI rating scale is designed to clarify the relationship between supervisory issues and deficiencies, and a firm's progress in remediation and mitigation efforts.

Conditionally Meets Expectations

In the proposed LFI rating system, the second highest rating category was ''Satisfactory Watch.'' This rating would have indicated that a firm was generally considered safe and sound; however, certain issues were sufficiently material that, if not resolved in a timely manner in the normal course of business, they would put the firm's prospects for remaining safe and sound through a range of conditions at risk. As noted in the proposal, the ''Satisfactory Watch'' rating was intended to be consistent with the Federal Reserve's practice of providing notice to firms that they are likely to be downgraded if identified weaknesses are not resolved in a timely manner.

The preamble to the proposal noted that the ''Satisfactory Watch'' rating was not intended to be used for a prolonged period; rather, firms would have had a specified timeframe to fully resolve issues leading to that rating (as is the case with all supervisory issues), but generally no longer than 18 months. Several commenters noted that many supervisory issues take longer than 18 months to resolve, and that resolution of certain issues requires substantial infrastructure investment and changes in processes and controls. As such, these commenters argued that the specified remediation timeframes in the ''Satisfactory Watch'' rating should be based on the specific facts and circumstances of the supervisory issue(s) in question, rather than limited to an 18-month period. These commenters also argued that a firm should not be downgraded provided the firm makes good faith efforts to remediate the issues and progress is made.

As in the proposal, the final ratings framework states that the Federal Reserve does not intend for a firm to be rated ''Conditionally Meets Expectations'' for a prolonged period. However, unlike the proposal, the final ratings framework does not establish a fixed timeline for how long a firm can be rated ''Conditionally Meets Expectations.'' Instead, the final ratings framework reflects an understanding that timelines will be issues-specific, noting that the Federal Reserve will work with the firm to develop an

[22] References to ''safe and sound'' or ''safety and soundness'' in the LFI rating system apply to a firm's consolidated organization as well as to its critical operations and banking offices.

[23] One comment requested removal of the term ''strong,'' which was used to describe practices related to controls. To provide the clarity requested by the commenter, the final terminology has been changed to use the term ''effective.''

appropriate timeframe during which the firm would be expected to resolve each supervisory issue leading to the ''Conditionally Meets Expectations'' rating. Further, the final ratings framework reflects an understanding that completion and validation of remediation activities for selected supervisory issues—such as those involving information technology modifications—will require an extended time horizon. In all instances, appropriate and effective risk mitigation techniques must be utilized in the interim to maintain safe-and-sound operations under a range of conditions until remediation activities are completed, validated, and fully operational.

One commenter recommended that the ''Satisfactory Watch'' rating should be permanent, rather than temporary, while another argued that the ''Satisfactory Watch'' rating should be used infrequently. The final LFI rating system acknowledges there are circumstances when a firm may be rated ''Conditionally Meets Expectations'' for a longer period of time if, for instance, the firm is close to completing resolution of the supervisory issues leading to the ''Conditionally Meets Expectations'' rating, but new issues may be identified that, taken alone, would be consistent with a ''Conditionally Meets Expectations'' rating. In this event, the firm may continue to be rated ''Conditionally Meets Expectations,'' provided the new issues do not reflect a pattern of deeper or prolonged capital planning or position weaknesses consistent with a ''Deficient'' rating.

The proposal would have provided that ''Satisfactory Watch'' would be appropriate when a firm could resolve the issue in a timely manner in the normal course of business. Commenters requested clarification on expectations regarding ''normal course of business.'' The final LFI rating system clarifies that ''normal course of business'' means that a firm has the ability to resolve these issues through measures that do not require a material change to the firm's business model or financial profile, or its governance, risk management, or internal control structures or practices.

Several commenters also argued that a firm rated ''Deficient'' should be upgraded to the ''Satisfactory Watch'' rating if the firm has remediated identified deficiencies but a validation process had not yet been completed. As indicated in the Deficient-1 section below, the final LFI framework indicates that a firm previously rated ''Deficient'' may be upgraded to ''Conditionally Meets Expectations'' if the firm's remediation and mitigation activities are sufficiently advanced so that its prospects for remaining safe and sound are no longer at significant risk, even if the firm has outstanding supervisory issues or is subject to an active enforcement action.

Deficient-1

In the proposal, the third rating category was ''Deficient-1,'' which would have indicated that, although the firm's current condition is not considered to be materially threatened, there were financial and/or operational deficiencies that put its prospects for remaining safe and sound through a range of conditions at significant risk. The final ratings framework maintains the name of the third rating category.

Under the proposed LFI rating system, a firm that received a rating of ''Deficient-1'' or ''Deficient-2'' in any component rating would not be considered ''well managed'' for purposes of the Bank Holding Company Act (BHC Act).[24] Several commenters suggested that the ''well managed'' determination should be made on the basis of an assessment of the firm as a whole, rather than the automatic consequence of any one component rating. One commenter argued that the separate, standalone composite rating should form the sole basis for determining a firm's ''well managed'' status.

Conditioning a firm's ''well managed'' status on all three rating categories reflects the judgment that a banking organization is not in satisfactory condition overall unless it is considered sound in each of the key areas of capital, liquidity, and governance and controls. Each rating category includes assessments of key aspects of a firm's practices and capabilities, including management, that are necessary to operate in a safe-and-sound manner. A ''Deficient'' rating in any of the components reflects the supervisory conclusion that financial or operational deficiencies have placed the firm's safety and soundness at significant risk, which would not warrant a firm being deemed ''well managed.'' Accordingly, the final LFI rating system maintains the proposed approach to determining whether a firm is ''well managed.''

Under current law, a firm must receive a ''Satisfactory'' risk management and composite rating in order to qualify as ''well managed.'' Several commenters argued that the proposed rating scale would introduce a more rigid standard compared with the RFI rating system, potentially making LFIs less likely to be considered ''well managed.'' In the Board's view, any rigidity is balanced by the introduction of the ''Conditionally Meets Expectations'' rating, which provides notice to firms that they are likely to be downgraded if identified weaknesses are not resolved in a timely manner.

The proposal noted that a ''Deficient-1'' component rating would often be an indication that the firm should be subject to either an informal or formal enforcement action, and may also result in the designation of the firm as being in ''troubled condition.'' [25] Several commenters requested clarity under what circumstances a ''Deficient-1'' rating would result in ''troubled condition'' status or a formal enforcement action.

Consistent with commenters' views, the final LFI rating system reflects that there is no presumption that a firm rated ''Deficient-1'' would be deemed to be in ''troubled condition.'' Whether a firm rated ''Deficient-1'' receives a ''troubled condition'' designation will be determined by the facts and circumstances at that firm. However, firms rated ''Deficient-1'' due to financial weaknesses in either capital or liquidity would be more likely to be deemed in ''troubled condition'' than firms rated ''Deficient-1'' due solely to issues of governance or controls.

While a commenter asked that a ''Deficient-1'' rating be an automatic bar to new or expansionary activity, others suggested that firms rated ''Deficient-1'' not be subject to any restrictions on growth. Consistent with the proposal, receiving a ''Deficient-1'' rating under the final LFI rating system would result in automatic consequences for a firm's ''well managed'' status, which would limit the firm's ability to engage in new or expansionary nonbanking activities. Further, as with the proposal, a ''Deficient-1'' rating in the final LFI rating system could be a barrier for a firm seeking the Federal Reserve's approval of a proposal to engage in new or expansionary activities, unless the firm can demonstrate that (i) it is making meaningful, sustained progress in resolving identified deficiencies and

[24] For purposes of determining whether a firm is considered to be ''well managed'' under section 2(o)(9) of the BHC Act, the Federal Reserve considers the three component ratings, taken together, to be equivalent to assigning a standalone composite rating. In addition, the RFI rating system designates the ''Risk Management'' rating as the ''management'' rating when making ''well managed'' determinations under section 2(o)(9)(A)(ii) of the BHC Act. *See* SR letter 04–8. In contrast, the LFI rating system would not designate any of the three component ratings as a ''management'' rating, because each component evaluates different areas of the firm's management.

[25] *See* 12 CFR 225.71(d).

issues; (ii) the proposed new or expansionary activities would not present a risk of exacerbating current deficiencies or issues or lead to new concerns; and (iii) the proposed activities would not distract the firm from remediating current deficiencies or issues.

Deficient-2

A ''Deficient-2'' rating indicates that financial and/or operational deficiencies materially threaten the firm's safety and soundness, or have already put the firm in an unsafe and unsound condition. The proposal noted that a firm with a ''Deficient-2'' component rating would be required to immediately (i) implement comprehensive corrective measures sufficient to restore and maintain appropriate capital planning capabilities and adequate capital positions; and (ii) demonstrate the sufficiency, credibility and readiness of contingency planning in the event of further deterioration of the firm's financial or operational strength or resiliency. It also noted that there is a strong presumption that a firm rated ''Deficient-2'' will be subject to a formal enforcement action by the Federal Reserve, and that the Federal Reserve would be unlikely to approve a proposal from a firm to engage in new or expansionary activities.

The final LFI rating system adopts the ''Deficient-2'' ratings category without change.

E. General Comments

Eliminating Subcomponent Ratings

The proposed LFI rating system described the areas of assessment under each component rating, but would not have assigned separate subcomponents for each area of assessment. A few commenters recommended that each of the three component ratings include subcomponent ratings, as used in the RFI rating system. These commenters argued that subcomponent ratings aid supervisory staff to consistently apply the component rating across institutions, and allow firms to more easily identify, communicate, and correct deficiencies across the organization.

Communicating a single rating in each component is intended to reinforce the Board's view that the strength of a firm's capital and liquidity position is integrated with the effectiveness the firm's capital planning and liquidity risk management, respectively, and the strength of a firm's risk management depends on the effectiveness of the board oversight. In developing the rating, the Federal Reserve will rely on firm-specific and horizontal examination work. Throughout the year, and in connection with its rating, firms will receive feedback relating to the supervisory activities that inform the ratings, which will provide firms with specific feedback relating to the elements of the rating.

Composite Rating

Several commenters asserted that the LFI rating system should include a separate, standalone composite rating in addition to the three component ratings. These commenters asserted that a composite rating would provide a fuller view of the health of each institution.

Unlike other supervisory rating systems, including the RFI rating system, the Federal Reserve will not assign a standalone composite rating under the LFI rating system. As noted in the proposal, assigning a standalone composite rating is not necessary because the three component ratings are designed to clearly communicate supervisory assessments and associated consequences for each of the core areas (capital, liquidity, and governance and controls). Further, the components identify those core areas that are necessary and critical to a firm's strength and resilience. It is unlikely that the assignment of a standalone composite rating would convey new or additional information regarding these supervisory assessments not already communicated by the three component ratings, and a standalone composite rating could dilute the clarity and impact of the component ratings. As such, the final LFI rating system does not include a separate standalone composite rating.

Disclosure and Challenge to Ratings

In accordance with the Federal Reserve's regulations governing confidential supervisory information,[26] ratings assigned under the proposed LFI rating system would have been communicated by the Federal Reserve to the firm but not disclosed publicly. One commenter requested that LFI rating components be publicly disclosed, as the public would benefit from additional supervisory disclosure regarding individual firms. The Board has traditionally maintained the confidentiality of supervisory ratings in order to preserve candor in communication between supervised institutions and the Board. For this reason, in accordance with the Federal Reserve's regulations governing confidential supervisory information, ratings assigned under the LFI rating system will be communicated by the Federal Reserve to the firm, but individual ratings will not be disclosed publicly. The Federal Reserve will continue to think broadly in considering ways to enhance transparency across its processes and communications in support of improved supervisory approaches and outcomes.

In addition, some commenters indicated that there should be a more effective process for firms to challenge and seek review of supervisory findings, such as additional opportunities to respond to adverse findings by examiners, and meetings with the Federal Reserve. The Federal Reserve is committed to engaging in ongoing dialogue with banking organizations regarding supervisory findings to ensure that firms understand supervisory expectations and that the Federal Reserve understands the way that firms think about their business and risks. The Board also is committed to maintaining an effective independent appellate process to allow institutions to seek review of material supervisory determinations. The Board recently issued a proposal that is out for comment and is currently considering comments on that proposal.[27]

V. Changes to Existing Regulations

References to holding company ratings are included in a number of the Federal Reserve's existing regulations. In certain cases, the regulations are narrowly constructed such that they contemplate only the assignment of a standalone composite rating using a numerical rating scale. This is consistent with the current RFI rating system but is not compatible with the LFI rating system. Three provisions in the Federal Reserve's existing regulations are written in this manner, including two in Regulation K and one in Regulation LL.

In Regulation K, § 211.2(z) includes a definition of ''well managed'' which, in part, requires a bank holding company to have received a composite rating of 1 or 2 at its most recent examination or review; and § 211.9(a)(2) requires an investor (which by definition can be a bank holding company) to have received a composite rating of at least 2 at its most recent examination in order to make investments under the general consent or limited general consent procedures contained in § 211.9(b) and (c).

In Regulation LL, § 238.54(a)(1) restricts savings and loan holding companies from commencing certain activities without the Federal Reserve's

[26] *See* 12 CFR 261.20.

[27] *See* 83 FR 8391 (February 27, 2018).

prior approval unless the company received a composite rating of 1 or 2 at its most recent examination.

To ensure that the Federal Reserve's regulations are consistent and compatible with all aspects of both the RFI rating system as well as the LFI rating system, the Federal Reserve is amending those three regulatory provisions so that they will apply to entities which receive numerical composite ratings as well as to entities which do not receive numerical composite ratings (including firms subject to the LFI rating system).[28] To satisfy the requirements of those provisions, firms that do not receive numerical composite ratings will have to be considered satisfactory under the LFI rating system. To be considered satisfactory, a firm would have to be rated ''Broadly Meets Expectations'' or ''Conditionally Meets Expectations'' for each component of the LFI rating system; a firm which is rated ''Deficient-1'' or lower for any component would not be considered satisfactory. This standard applies to any provision contained in the Federal Reserve's regulations, which requires or refers to a firm having a satisfactory composite rating.

VI. Comparison of the RFI and LFI Rating Systems

As compared to the RFI rating system, the proposed LFI rating system did not include an explicit assessment of a banking organization's ability to protect depository institutions from the activities of non-depository or capital market subsidiaries. The commenter suggested the Board revise the proposal to recognize the importance of this concept.

In response to the commenter, the final LFI rating system acknowledges that a banking organization is expected to ensure that the consolidated organization, including its critical operations and banking offices, remains safe and sound through a range of potentially stressful conditions.

The final LFI rating system includes several structural changes from the RFI rating system. The following table provides a broad comparison between the two rating systems.

RFI rating system	LFI rating system
R—Risk Management	
An evaluation of the ability of the bank holding company's board of directors and senior management to identify, measure, monitor, and control risk.	Assessment of the effectiveness of a firm's governance and risk management practices is central to the Governance and Controls component rating. The Governance and Controls component rating evaluates a firm's effectiveness in aligning strategic business objectives with risk management capabilities; maintaining effective and independent risk management and control functions, including internal audit; promoting compliance with laws and regulations, including those related to consumer protection; and otherwise providing for the ongoing resiliency of the firm.
The rating is supported by four subcomponent ratings ..... • Board and Senior Management Oversight • Policies, Procedures, and Limits • Risk Monitoring and Management Information Systems • Internal Controls	Governance and risk management practices specifically related to maintaining financial strength and resilience are also incorporated into the Capital Planning and Positions and Liquidity Risk Management and Positions component ratings.
F—Financial Condition	
An evaluation of the consolidated organization's financial strength	Assessment of a firm's financial strength and resilience is specifically evaluated through the Capital Planning and Positions and Liquidity Risk Management and Positions component ratings.
The rating is supported by four subcomponent ratings ..... • Capital Adequacy • Asset Quality • Earnings • Liquidity	These component ratings also assess the effectiveness of associated planning and risk management processes, and the sufficiency of related positions. Although asset quality and earnings are not rated separately, they continue to be important elements in assessing a firm's safety and soundness and resiliency, and are important considerations within each of the LFI component ratings.
I—Impact	
An assessment of the potential impact of the firm's nondepository entities on its subsidiary depository institution(s).	Although a separate ''Impact'' rating will not be assigned, the LFI rating system will assess a firm's ability to protect the safety and soundness of its subsidiary depository institutions, including whether the firm can provide financial and operational strength to its subsidiary depository institutions.[29]
D—Depository Institutions	
Generally reflects the composite CAMELS rating assigned by the primary supervisor of the subsidiary depository institution(s).[30]	The LFI rating system would not assign a separate rating for a firm's depository institution subsidiaries. The Federal Reserve will continue to rely to the fullest extent possible on supervisory assessments developed by the primary supervisor of the subsidiary depository institution(s).

[28] The Board may propose additional necessary revisions to its regulations resulting from the adoption of a final LFI rating system.

RFI rating system	LFI rating system
C—Composite Rating	
The overall composite assessment of the bank holding company as reflected by the R, F, and I ratings, and supported by examiner judgment with respect to the relative importance of each component to the safe and sound operation of the bank holding company..	A standalone composite rating will not be assigned. The three LFI component ratings are designed to clearly communicate supervisory assessments and associated consequences for each of the core areas (capital, liquidity, and governance and controls) that are considered critical to an LFI's strength and resilience. For purposes of determining whether a firm is ''well managed,'' each component must be rated either ''Broadly Meets Expectations'' or ''Conditionally Meets Expectations'' in order for a firm to be deemed ''well managed.''

VII. Regulatory Analysis

A. Paperwork Reduction Act

There is no collection of information required by this proposal that would be subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* generally requires that, in connection with a proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis (IRFA). The Board solicited public comment on the LFI rating system in a notice of proposed rulemaking and has since considered the potential impact of this final rule on small entities in accordance with section 604 of the RFA. Based on the Board's analysis, and for the reasons stated below, the Board believes the final rule will not have a significant economic impact on a substantial number of small entities.

The RFA requires an agency to prepare a final regulatory flexibility analysis (FRFA) unless the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The FRFA must contain: (1) A statement of the need for, and objectives of, the rule; (2) a statement of the significant issues raised by the public comments in response to the IRFA, a statement of the agency's assessment of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any changes made to the proposed rule in the final rule as a result of the comments; (4) a description of an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (5) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and type of professional skills necessary for preparation of the report or record; and (6) a description of the steps the agency has taken to minimize the economic impact on small entities, including a statement for selecting or rejecting the other significant alternatives to the rule considered by the agency.

The final rule adopts a new holding company rating system for large financial institutions, and amend the Board's Regulations K and LL to ensure the Board's regulations are compatible with all aspects of the LFI rating system, but will not change the operation of those regulations for any entity that is not subject to the LFI rating system. Commenters did not raise any issues in response to the IRFA. In addition, the Chief Counsel for Advocacy of the Small Business Administration did not file any comments in response to the proposed rule.

Under regulations issued by the Small Business Administration (SBA), a ''small entity'' includes a depository institution, bank holding company, or savings and loan holding company with assets of $550 million or less (small banking organizations). As discussed in the **SUPPLEMENTARY INFORMATION**, the final rule will apply to all bank holding companies with total consolidated assets of $100 billion or more; all non-insurance, non-commercial savings and loan holding companies with total consolidated assets of $100 billion or more; and U.S. intermediate holding companies of foreign banking organizations with total consolidated assets of $50 billion or more.

Companies that are subject to the final rule therefore substantially exceed the $550 million asset threshold at which a banking entity is considered a ''small entity'' under SBA regulations. Because the final rule does not apply to any company with assets of $550 million or less, the final rule would not apply to any ''small entity'' for purposes of the RFA.

There are no projected reporting, recordkeeping, or other compliance requirements associated with the final rule. As discussed above, the final rule does not apply to small entities.

The Board does not believe that the final rule duplicates, overlaps, or conflicts with any other Federal Rules. In addition, the Board does not believe there are significant alternatives to the final rule that have less economic impact on small entities. In light of the foregoing, the Board does not believe the final rule will have a significant economic impact on a substantial number of small entities.

C. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the Board to use plain language in all proposed and final rules published after January 1, 2000. The Board received no comments on these matters and believes that the final rule is written plainly and clearly.

List of Subjects

12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 238

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons stated in the preamble, the Board amends 12 CFR parts 211 and 238 as follows:

[29] *See* Sections 616 of Dodd-Frank Act (financial strength), 12 CFR 225.4 of the Board's Regulation Y, and 12 CFR 238.8 of the Board's Regulation LL.

[30] *See* SR letter 96–38, ''Uniform Financial Institutions Rating System,'' at *http://www.federalreserve.gov/boarddocs/srletters/1996/sr9638.htm.*

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

■ 1. The authority citations for part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.,* 1818, 1835a, 1841 *et seq.,* 3101 *et seq.,* 3901 *et seq.,* and 5101 *et seq.;* 15 U.S.C. 1681s, 1681w, 6801 and 6805.

■ 2. Section 211.2 is amended by revising paragraph (z) to read as follows:

§ 211.2 Definitions.

* * * * *

(z) *Well managed* means that the Edge or agreement corporation, any parent insured bank, and the bank holding company either received a composite rating of 1 or 2 or is considered satisfactory under the applicable rating system, and has at least a satisfactory rating for management if such a rating is given, at their most recent examination or review.

■ 3. Section 211.9 is amended by revising paragraph (a)(2) to read as follows:

§ 211.9 Investment procedures.

(a) * * *

(2) *Composite rating.* Except as the Board may otherwise determine, in order for an investor to make investments under the general consent or limited general consent procedures of paragraphs (b) and (c) of this section, at the most recent examination the investor and any parent insured bank must have either received a composite rating of at least 2 or be considered satisfactory under the applicable rating system.

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PART 238—SAVINGS AND LOAN HOLDING COMPANIES (REGULATION LL)

■ 4. The authority citations for part 238 continues to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462, 1462a, 1463, 1464, 1467, 1467a, 1468, 1813, 1817, 1829e, 1831i, 1972; 15 U.S.C. 78*l*.

■ 5. Section 238.54 is amended by revising paragraph (a)(1) to read as follows:

§ 238.54 Permissible bank holding company activities of savings and loan holding companies.

(a) * * *

(1) The holding company received a rating of satisfactory or above prior to January 1, 2008, or thereafter, either received a composite rating of ''1'' or ''2'' or be considered satisfactory under the applicable rating system in its most recent examination, and is not in a troubled condition as defined in § 238.72, and the holding company does not propose to commence the activity by an acquisition (in whole or in part) of a going concern; or

* * * * *

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix A—Text of Large Financial Institution Rating System

A. Overview

Each large financial institution (LFI) is expected to ensure that the consolidated organization (or the combined U.S. operations in the case of foreign banking organizations), including its critical operations and banking offices, remain safe and sound and in compliance with laws and regulations, including those related to consumer protection.[1] The LFI rating system provides a supervisory evaluation of whether a covered firm possesses sufficient financial and operational strength and resilience to maintain safe-and-sound operations through a range of conditions, including stressful ones.[2] The LFI rating system applies to bank holding companies with total consolidated assets of $100 billion or more; all non-insurance, non-commercial savings and loan holding companies with total consolidated assets of $100 billion or more; and U.S. intermediate holding companies of foreign banking organizations with combined U.S. assets of $50 billion or more established pursuant to the Federal Reserve's Regulation YY.[3]

The LFI rating system is designed to:

- Fully align with the Federal Reserve's current supervisory programs and practices, which are based upon the LFI supervision framework's core objectives of reducing the probability of LFIs failing or experiencing material distress and reducing the risk to U.S. financial stability;
- Enhance the clarity and consistency of supervisory assessments and communications of supervisory findings and implications; and
- Provide transparency related to the supervisory consequences of a given rating.

The LFI rating system is comprised of three components:

- *Capital Planning and Positions:* An evaluation of (i) the effectiveness of a firm's governance and planning processes used to determine the amount of capital necessary to cover risks and exposures, and to support activities through a range of conditions and events; and (ii) the sufficiency of a firm's capital positions to comply with applicable regulatory requirements and to support the firm's ability to continue to serve as a financial intermediary through a range of conditions.
- *Liquidity Risk Management and Positions:* An evaluation of (i) the effectiveness of a firm's governance and risk management processes used to determine the amount of liquidity necessary to cover risks and exposures, and to support activities through a range of conditions; and (ii) the sufficiency of a firm's liquidity positions to comply with applicable regulatory requirements and to support the firm's ongoing obligations through a range of conditions.
- *Governance and Controls:* An evaluation of the effectiveness of a firm's (i) board of directors,[4] (ii) management of business lines and independent risk management and controls,[5] and (iii) recovery planning (only for domestic firms that are subject to the Board's Large Institution Supervision Coordinating Committee (LISCC) Framework).[6] This rating assesses a firm's

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[1] See SR letter 12–17/CA letter 12–14, ''Consolidated Supervisory Framework for Large Financial Institutions,'' at *http://www.federalreserve.gov/bankinforeg/srletters/sr1217.htm.*

Hereinafter, when ''safe and sound'' or ''safety and soundness'' is used in this framework, related expectations apply to the consolidated organization and the firm's critical operations and banking offices.

''Critical operations'' are a firm's operations, including associated services, functions and support, the failure or discontinuance of which, in the view of the firm or the Federal Reserve, would pose a threat to the financial stability of the United States.

''Banking offices'' are defined as U.S. depository institution subsidiaries, as well as the U.S. branches and agencies of foreign banking organizations.

[2] ''Financial strength and resilience'' is defined as maintaining effective capital and liquidity governance and planning processes, and sufficiency of related positions, to provide for the continuity of the consolidated organization (including its critical operations and banking offices) through a range of conditions.

''Operational strength and resilience'' is defined as maintaining effective governance and controls to provide for the continuity of the consolidated organization (including its critical operations and banking offices) and to promote compliance with laws and regulations, including those related to consumer protection, through a range of conditions.

References to ''financial or operational'' weaknesses or deficiencies implicate a firm's financial or operational strength and resilience.

[3] Total consolidated assets will be calculated based on the average of the firm's total consolidated assets in the four most recent quarters as reported on the firm's quarterly financial reports filed with the Federal Reserve. A firm will continue to be rated under the LFI rating system until it has less than $95 billion in total consolidated assets, based on the average total consolidated assets as reported on the firm's four most recent quarterly financial reports filed with the Federal Reserve. As noted in the proposal, the Federal Reserve may determine to apply the RFI rating system or another applicable rating system in certain limited circumstances.

[4] References to ''board'' or ''board of directors'' in this framework includes the equivalent to a board of directors, as appropriate, as well as committees of the board of directors or the equivalent thereof, as appropriate.

At this time, recovery planning expectations only apply to domestic bank holding companies subject to the Federal Reserve's LISCC supervisory framework. Should the Federal Reserve expand the scope of recovery planning expectations to encompass additional firms, this rating will reflect such expectations for the broader set of firms.

[5] The evaluation of the effectiveness of management of business lines would include management of critical operations.

[6] There are eight domestic firms in the LISCC portfolio: (1) Bank of America Corporation; (2) Bank of New York Mellon Corporation; (3) Citigroup,

effectiveness in aligning strategic business objectives with the firm's risk appetite and risk management capabilities; maintaining effective and independent risk management and control functions, including internal audit; promoting compliance with laws and regulations, including those related to consumer protection; and otherwise planning for the ongoing resiliency of the firm.[7]

B. Assignment of the LFI Component Ratings

Each LFI component rating is assigned along a four-level scale:

• *Broadly Meets Expectations:* A firm's practices and capabilities broadly meet supervisory expectations, and the firm possesses sufficient financial and operational strength and resilience to maintain safe-and-sound operations through a range of conditions. The firm may be subject to identified supervisory issues requiring corrective action. These issues are unlikely to present a threat to the firm's ability to maintain safe-and-sound operations through a range of conditions.

• *Conditionally Meets Expectations:* Certain, material financial or operational weaknesses in a firm's practices or capabilities may place the firm's prospects for remaining safe and sound through a range of conditions at risk if not resolved in a timely manner during the normal course of business.

The Federal Reserve does not intend for a firm to be assigned a ''Conditionally Meets Expectations'' rating for a prolonged period, and will work with the firm to develop an appropriate timeframe to fully resolve the issues leading to the rating assignment and merit upgrade to a ''Broadly Meets Expectations'' rating.

A firm is assigned a ''Conditionally Meets Expectations'' rating—as opposed to a ''Deficient'' rating—when it has the ability to resolve these issues through measures that do not require a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices. Failure to resolve the issues in a timely manner would most likely result in the firm's downgrade to a ''Deficient'' rating, since the inability to resolve the issues would indicate that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

It is recognized that completion and validation of remediation activities for select supervisory issues—such as those involving information technology modifications—may require an extended time horizon. In all instances, appropriate and effective risk mitigation techniques must be utilized in the interim to maintain safe-and-sound operations under a range of conditions until remediation activities are completed, validated, and fully operational.

• *Deficient-1:* Financial or operational deficiencies in a firm's practices or capabilities put the firm's prospects for remaining safe and sound through a range of conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require the firm to make a material change to its business model or financial profile, or its practices or capabilities.

A firm's failure to resolve the issues in a timely manner that gave rise to a ''Conditionally Meets Expectations'' rating would most likely result in its downgrade to a ''Deficient'' rating.

A firm with a ''Deficient-1'' rating is required to take timely corrective action to correct financial or operational deficiencies and to restore and maintain its safety and soundness and compliance with laws and regulations, including those related to consumer protection. There is a strong presumption that a firm with a ''Deficient-1'' rating will be subject to an informal or formal enforcement action, and this rating assignment could be a barrier for a firm seeking Federal Reserve approval to engage in new or expansionary activities.

• *Deficient-2:* Financial or operational deficiencies in a firm's practices or capabilities present a threat to the firm's safety and soundness, or have already put the firm in an unsafe and unsound condition.

A firm with a ''Deficient-2'' rating is required to immediately implement comprehensive corrective measures, and demonstrate the sufficiency of contingency planning in the event of further deterioration. There is a strong presumption that a firm with a ''Deficient-2'' rating will be subject to a formal enforcement action, and the Federal Reserve would be unlikely to approve any proposal from a firm with this rating to engage in new or expansionary activities.

The Federal Reserve will take into account a number of individual elements of a firm's practices, capabilities and performance when making each component rating assignment. The weighting of an individual element in assigning a component rating will depend on its impact on the firm's safety, soundness and resilience as provided for in the LFI rating system definitions. For example, for purposes of the Governance and Controls rating, a limited number of significant deficiencies—or even just one significant deficiency—noted for management of a single material business line could be viewed as sufficiently important to warrant a ''Deficient-1'' for the Governance and Controls component rating, even if the firm meets supervisory expectations under the Governance and Controls component in all other respects.

Under the LFI rating system, a firm must be rated ''Broadly Meets Expectations'' or ''Conditionally Meets Expectations'' for each of the three component ratings (Capital, Liquidity, Governance and Controls) to be considered ''well managed'' in accordance with various statutes and regulations.[8] A ''well managed'' firm has sufficient financial and operational strength and resilience to maintain safe-and-sound operations through a range of conditions, including stressful ones.

C. LFI Rating Components

The LFI rating system is comprised of three component ratings:[9]

1. Capital Planning and Positions Component Rating

The Capital Planning and Positions component rating evaluates (i) the effectiveness of a firm's governance and planning processes used to determine the amount of capital necessary to cover risks and exposures, and to support activities through a range of conditions; and (ii) the sufficiency of a firm's capital positions to comply with applicable regulatory requirements and to support the firm's ability to continue to serve as a financial intermediary through a range of conditions.

In developing this rating, the Federal Reserve evaluates:

• *Capital Planning:* The extent to which a firm maintains sound capital planning practices through effective governance and oversight; effective risk management and controls; maintenance of updated capital policies and contingency plans for addressing potential shortfalls; and incorporation of appropriately stressful conditions into capital planning and projections of capital positions; and

• *Capital Positions:* The extent to which a firm's capital is sufficient to comply with regulatory requirements, and to support its ability to meet its obligations to depositors, creditors, and other counterparties and continue to serve as a financial intermediary through a range of conditions.

Definitions for the Capital Planning and Positions Component Rating

Broadly Meets Expectations

A firm's capital planning and positions broadly meet supervisory expectations and support maintenance of safe-and-sound operations. Specifically:

• The firm is capable of producing sound assessments of capital adequacy through a range of conditions; *and*

• The firm's current and projected capital positions comply with regulatory requirements, and support its ability to absorb current and potential losses, to meet obligations, and to continue to serve as a financial intermediary through a range of conditions.

A firm rated ''Broadly Meets Expectations'' may be subject to identified supervisory issues requiring corrective action. However, these issues are unlikely to present a threat to the firm's ability to maintain safe-and-sound operations through a range of potentially stressful conditions.

Inc.; (4) Goldman Sachs Group, Inc.; (5) JP Morgan Chase & Co.; (6) Morgan Stanley; (7) State Street Corporation; and (8) Wells Fargo & Company. In this guidance, these eight firms may collectively be referred to as ''domestic LISCC firms.''

[7] ''Risk appetite'' is defined as the aggregate level and types of risk the board and senior management are willing to assume to achieve the firm's strategic business objectives, consistent with applicable capital, liquidity, and other requirements and constraints.

[8] 12 U.S.C. 1841 *et seq.* and 12 U.S.C. 1461 *et seq.* *See, e.g.,* 12 CFR 225.4(b)(6), 225.14, 225.22(a), 225.23, 225.85, and 225.86; 12 CFR 211.9(b), 211.10(a)(14), and 211.34; and 12 CFR 223.41.

[9] There may be instances where deficiencies or supervisory issues may be relevant to the Federal Reserve's assessment of more than one component area. As such, the LFI rating will reflect these deficiencies or issues within multiple rating components when necessary to provide a comprehensive supervisory assessment.

A firm that does not meet the capital planning and position expectations associated with a ''Broadly Meets Expectations'' rating will be rated ''Conditionally Meets Expectations,'' ''Deficient-1,'' or ''Deficient-2,'' and subject to potential consequences as outlined below.

Conditionally Meets Expectations

Certain, material financial or operational weaknesses in a firm's capital planning or positions may place the firm's prospects for remaining safe and sound through a range of conditions at risk if not resolved in a timely manner during the normal course of business.

Specifically, if left unresolved, these weaknesses:

- May threaten the firm's ability to produce sound assessments of capital adequacy through a range of conditions; and/or
- May result in the firm's projected capital positions being insufficient to absorb potential losses, comply with regulatory requirements, and support the firm's ability to meet current and prospective obligations and to continue to serve as a financial intermediary through a range of conditions.

The Federal Reserve does not intend for a firm to be rated ''Conditionally Meets Expectations'' for a prolonged period. The firm has the ability to resolve these issues through measures that do not require a material change to the firm's business model or financial profile, or its governance, risk management, or internal control structures or practices. The Federal Reserve will work with the firm to develop an appropriate timeframe during which the firm would be required to resolve each supervisory issue leading to the ''Conditionally Meets Expectations'' rating.

The Federal Reserve will closely monitor the firm's remediation and mitigation activities; in most instances, the firm will either:

(i) Resolve the issues in a timely manner and, if no new material supervisory issues arise, be upgraded to a ''Broadly Meets Expectations'' rating because the firm's capital planning practices and related positions would broadly meet supervisory expectations; or

(ii) Fail to resolve the issues in a timely manner and be downgraded to a ''Deficient-1'' rating, because the inability to resolve the issues would indicate that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

It is possible that a firm may be close to completing resolution of the supervisory issues leading to the ''Conditionally Meets Expectations'' rating, but new issues are identified that, taken alone, would be consistent with a ''Conditionally Meets Expectations'' rating. In this event, the firm may continue to be rated ''Conditionally Meets Expectations,'' provided the new issues do not reflect a pattern of deeper or prolonged capital planning or position weaknesses consistent with a ''Deficient'' rating.

A ''Conditionally Meets Expectations'' rating may be assigned to a firm that meets the above definition regardless of its prior rating. A firm previously rated ''Deficient-1'' may be upgraded to ''Conditionally Meets Expectations'' if the firm's remediation and mitigation activities are sufficiently advanced so that the firm's prospects for remaining safe and sound are no longer at significant risk, even if the firm has outstanding supervisory issues or is subject to an active enforcement action.

Deficient-1

Financial or operational deficiencies in a firm's capital planning or positions put the firm's prospects for remaining safe and sound through a range of conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require a material change to the firm's business model or financial profile, or its capital planning practices.

Specifically, although the firm's current condition is not considered to be materially threatened:

- Deficiencies in the firm's capital planning processes are not effectively mitigated. These deficiencies limit the firm's ability to effectively assess capital adequacy through a range of conditions; and/or
- The firm's projected capital positions may be insufficient to absorb potential losses and to support its ability to meet current and prospective obligations and serve as a financial intermediary through a range of conditions.

Supervisory issues that place the firm's safety and soundness at significant risk, and where resolution is likely to require steps that clearly go beyond the normal course of business—such as issues requiring a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices—would generally warrant assignment of a ''Deficient-1'' rating.

A ''Deficient-1'' rating may be assigned to a firm regardless of its prior rating. A firm previously rated ''Broadly Meets Expectations'' may be downgraded to ''Deficient-1'' when supervisory issues are identified that place the firm's prospects for maintaining safe-and-sound operations through a range of potentially stressful conditions at significant risk. A firm previously rated ''Conditionally Meets Expectations'' may be downgraded to ''Deficient-1'' when the firm's inability to resolve supervisory issues in a timely manner indicates that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

To address these financial or operational deficiencies, the firm is required to take timely corrective action to restore and maintain its capital planning and positions consistent with supervisory expectations. There is a strong presumption that a firm rated ''Deficient-1'' will be subject to an informal or formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-1'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. A ''Deficient-1'' rating could be a barrier for a firm seeking Federal Reserve approval of a proposal to engage in new or expansionary activities, unless the firm can demonstrate that (i) it is making meaningful, sustained progress in resolving identified deficiencies and issues; (ii) the proposed new or expansionary activities would not present a risk of exacerbating current deficiencies or issues or lead to new concerns; and (iii) the proposed activities would not distract the firm from remediating current deficiencies or issues.

Deficient-2

Financial or operational deficiencies in a firm's capital planning or positions present a threat to the firm's safety and soundness, or have already put the firm in an unsafe and unsound condition.

Specifically, as a result of these deficiencies:

- The firm's capital planning processes are insufficient to effectively assess the firm's capital adequacy through a range of conditions; and/or
- The firm's current or projected capital positions are insufficient to absorb current or potential losses, and to support the firm's ability to meet current and prospective obligations and serve as a financial intermediary through a range of conditions.

To address these deficiencies, the firm is required to immediately (i) implement comprehensive corrective measures sufficient to restore and maintain appropriate capital planning capabilities and adequate capital positions; and (ii) demonstrate the sufficiency, credibility and readiness of contingency planning in the event of further deterioration of the firm's financial or operational strength or resiliency. There is a strong presumption that a firm rated ''Deficient-2'' will be subject to a formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-2'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. The Federal Reserve would be unlikely to approve any proposal from a firm rated ''Deficient-2'' to engage in new or expansionary activities.

2. Liquidity Risk Management and Positions Component Rating

The Liquidity Risk Management and Positions component rating evaluates (i) the effectiveness of a firm's governance and risk management processes used to determine the amount of liquidity necessary to cover risks and exposures, and to support activities through a range of conditions; and (ii) the sufficiency of a firm's liquidity positions to comply with applicable regulatory requirements and to support the firm's ongoing obligations through a range of conditions.

In developing this rating, the Federal Reserve evaluates:

- *Liquidity Risk Management:* The extent to which a firm maintains sound liquidity risk management practices through effective governance and oversight; effective risk management and controls; maintenance of updated liquidity policies and contingency plans for addressing potential shortfalls; and incorporation of appropriately stressful conditions into liquidity planning and projections of liquidity positions; and
- *Liquidity Positions:* The extent to which a firm's liquidity is sufficient to comply with

regulatory requirements, and to support its ability to meet current and prospective obligations to depositors, creditors and other counterparties through a range of conditions.

Definitions for the Liquidity Risk Management and Positions Component Rating

Broadly Meets Expectations

A firm's liquidity risk management and positions broadly meet supervisory expectations and support maintenance of safe-and-sound operations. Specifically:

- The firm is capable of producing sound assessments of liquidity adequacy through a range of conditions; *and*
- The firm's current and projected liquidity positions comply with regulatory requirements, and support its ability to meet current and prospective obligations and to continue to serve as a financial intermediary through a range of conditions.

A firm rated ''Broadly Meets Expectations'' may be subject to identified supervisory issues requiring corrective action. However, these issues are unlikely to present a threat to the firm's ability to maintain safe-and-sound operations through a range of potentially stressful conditions.

A firm that does not meet the liquidity risk management and position expectations associated with a ''Broadly Meets Expectations'' rating will be rated ''Conditionally Meets Expectations,'' ''Deficient-1,'' or ''Deficient-2,'' and subject to potential consequences as outlined below.

Conditionally Meets Expectations

Certain, material financial or operational weaknesses in a firm's liquidity risk management or positions may place the firm's prospects for remaining safe and sound through a range of conditions at risk if not resolved in a timely manner during the normal course of business.

Specifically, if left unresolved, these weaknesses:

- May threaten the firm's ability to produce sound assessments of liquidity adequacy through a range of conditions; and/or
- May result in the firm's projected liquidity positions being insufficient to comply with regulatory requirements, and support its ability to meet current and prospective obligations and to continue to serve as a financial intermediary through a range of conditions.

The Federal Reserve does not intend for a firm to be rated ''Conditionally Meets Expectations'' for a prolonged period. The firm has the ability to resolve these issues through measures that do not require a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices. The Federal Reserve will work with the firm to develop an appropriate timeframe during which the firm would be required to resolve each supervisory issue leading to the ''Conditionally Meets Expectations'' rating.

The Federal Reserve will closely monitor the firm's remediation and mitigation activities; in most instances, the firm will either:

(i) Resolve the issues in a timely manner and, if no new material supervisory issues arise, and be upgraded to a ''Broadly Meets Expectations'' rating because the firm's liquidity risk management practices and related positions would broadly meet supervisory expectations; or

(ii) Fail to resolve the issues in a timely manner and be downgraded to a ''Deficient-1'' rating, because the firm's inability to resolve those issues would indicate that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

It is possible that a firm may be close to completing resolution of the supervisory issues leading to the ''Conditionally Meets Expectations'' rating, but new issues are identified that, taken alone, would be consistent with a ''Conditionally Meets Expectations'' rating. In this event, the firm may continue to be rated ''Conditionally Meets Expectations,'' provided the new issues do not reflect a pattern of deeper or prolonged capital planning or position weaknesses consistent with a ''Deficient'' rating.

A ''Conditionally Meets Expectations'' rating may be assigned to a firm that meets the above definition regardless of its prior rating. A firm previously rated ''Deficient-1'' may be upgraded to ''Conditionally Meets Expectations'' if the firm's remediation and mitigation activities are sufficiently advanced so that the firm's prospects for remaining safe and sound are no longer at significant risk, even if the firm has outstanding supervisory issues or is subject to an active enforcement action.

Deficient-1

Financial or operational deficiencies in a firm's liquidity risk management or positions put the firm's prospects for remaining safe and sound through a range of conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require a material change to the firm's business model or financial profile, or its liquidity risk management practices.

Specifically, although the firm's current condition is not considered to be materially threatened:

- Deficiencies in the firm's liquidity risk management processes are not effectively mitigated. These deficiencies limit the firm's ability to effectively assess liquidity adequacy through a range of conditions; and/or
- The firm's projected liquidity positions may be insufficient to support its ability to meet prospective obligations and serve as a financial intermediary through a range of conditions.

Supervisory issues that place the firm's safety and soundness at significant risk, and where resolution is likely to require steps that clearly go beyond the normal course of business—such as issues requiring a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices—would generally warrant assignment of a ''Deficient-1'' rating.

A ''Deficient-1'' rating may be assigned to a firm regardless of its prior rating. A firm previously rated ''Broadly Meets Expectations'' may be downgraded to ''Deficient-1'' when supervisory issues are identified that place the firm's prospects for maintaining safe-and-sound operations through a range of potentially stressful conditions at significant risk. A firm previously rated ''Conditionally Meets Expectations'' may be downgraded to ''Deficient-1'' when the firm's inability to resolve supervisory issues in a timely manner indicates that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

To address these financial or operational deficiencies, the firm is required to take timely corrective action to restore and maintain its liquidity risk management and positions consistent with supervisory expectations. There is a strong presumption that a firm rated ''Deficient-1'' will be subject to an informal or formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-1'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. A ''Deficient-1'' rating could be a barrier for a firm seeking Federal Reserve approval of a proposal to engage in new or expansionary activities, unless the firm can demonstrate that (i) it is making meaningful, sustained progress in resolving identified deficiencies and issues; (ii) the proposed new or expansionary activities would not present a risk of exacerbating current deficiencies or issues or lead to new concerns; and (iii) the proposed activities would not distract the firm from remediating current deficiencies or issues.

Deficient-2

Financial or operational deficiencies in a firm's liquidity risk management or positions present a threat to the firm's safety and soundness, or have already put the firm in an unsafe and unsound condition.

Specifically, as a result of these deficiencies:

- The firm's liquidity risk management processes are insufficient to effectively assess the firm's liquidity adequacy through a range of conditions; and/or
- The firm's current or projected liquidity positions are insufficient to support the firm's ability to meet current and prospective obligations and serve as a financial intermediary through a range of conditions.

To address these deficiencies, the firm is required to immediately (i) implement comprehensive corrective measures sufficient to restore and maintain appropriate liquidity risk management capabilities and adequate liquidity positions; and (ii) demonstrate the sufficiency, credibility and readiness of contingency planning in the event of further deterioration of the firm's financial or operational strength or resiliency. There is a strong presumption that a firm rated ''Deficient-2'' will be subject to a formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-2'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. The Federal Reserve would be unlikely to approve any proposal

from a firm rated ''Deficient-2'' to engage in new or expansionary activities.

3. Governance and Controls Component Rating

The Governance and Controls component rating evaluates the effectiveness of a firm's (i) board of directors, (ii) management of business lines and independent risk management and controls, and (iii) recovery planning (for domestic LISCC firms only). This rating assesses a firm's effectiveness in aligning strategic business objectives with the firm's risk appetite and risk management capabilities; maintaining effective and independent risk management and control functions, including internal audit; promoting compliance with laws and regulations, including those related to consumer protection; and otherwise providing for the ongoing resiliency of the firm.

In developing this rating, the Federal Reserve evaluates:

• *Effectiveness of the Board of Directors:* The extent to which the board exhibits attributes that are consistent with those of effective boards in carrying out its core roles and responsibilities, including: (i) Setting a clear, aligned, and consistent direction regarding the firm's strategy and risk appetite; (ii) directing senior management regarding the board's information; (iii) overseeing and holding senior management accountable, (iv) supporting the independence and stature of independent risk management and internal audit; and (v) maintaining a capable board composition and governance structure.

• *Management of Business Lines and Independent Risk Management and Controls*

The extent to which:

○ Senior management effectively and prudently manages the day-to-day operations of the firm and provides for ongoing resiliency; implements the firm's strategy and risk appetite; maintains an effective risk management framework and system of internal controls; and promotes prudent risk taking behaviors and business practices, including compliance with laws and regulations, including those related to consumer protection.

○ Business line management executes business line activities consistent with the firm's strategy and risk appetite; identifies and manages risks; and ensures an effective system of internal controls for its operations.

○ Independent risk management effectively evaluates whether the firm's risk appetite appropriately captures material risks and is consistent with the firm's risk management capacity; establishes and monitors risk limits that are consistent with the firm's risk appetite; identifies and measures the firm's risks; and aggregates, assesses and reports on the firm's risk profile and positions. Additionally, the firm demonstrates that its internal controls are appropriate and tested for effectiveness. Finally, internal audit effectively and independently assesses the firm's risk management framework and internal control systems, and reports findings to senior management and the firm's audit committee.

• *Recovery Planning (domestic LISCC firms only):* The extent to which recovery planning processes effectively identify options that provide a reasonable chance of a firm being able to remedy financial weakness and restore market confidence without extraordinary official sector support.

Definitions for the Governance and Controls Component Rating

Broadly Meets Expectations

A firm's governance and controls broadly meet supervisory expectations and support maintenance of safe-and-sound operations.

Specifically, the firm's practices and capabilities are sufficient to align strategic business objectives with its risk appetite and risk management capabilities,[10] maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations (including those related to consumer protection); and otherwise provide for the firm's ongoing financial and operational resiliency through a range of conditions.

A firm rated ''Broadly Meets Expectations'' may be subject to identified supervisory issues requiring corrective action. However, these issues are unlikely to present a threat to the firm's ability to maintain safe-and-sound operations through a range of potentially stressful conditions.

A firm that does not meet supervisory expectations associated with a ''Broadly Meets Expectations'' rating will be rated ''Conditionally Meets Expectations,'' ''Deficient-1,'' or ''Deficient-2,'' and subject to potential consequences, as outlined below.

Conditionally Meets Expectations

Certain, material financial or operational weaknesses in a firm's governance and controls practices may place the firm's prospects for remaining safe and sound through a range of conditions at risk if not resolved in a timely manner during the normal course of business.

Specifically, if left unresolved, these weaknesses may threaten the firm's ability to align strategic business objectives with the firm's risk appetite and risk management capabilities; maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations (including those related to consumer protection); or otherwise provide for the firm's ongoing resiliency through a range of conditions.

The Federal Reserve does not intend for a firm to be rated ''Conditionally Meets Expectations'' for a prolonged period. The firm has the ability to resolve these issues through measures that do not require a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices. The Federal Reserve will work with the firm to develop an appropriate timeframe during which the firm would be required to resolve each supervisory issue leading to the ''Conditionally Meets Expectations'' rating.

The Federal Reserve will closely monitor the firm's remediation and mitigation activities; in most instances, the firm will either:

(i) Resolve the issues in a timely manner and, if no new material supervisory issues arise, and be upgraded to a ''Broadly Meets Expectations'' rating because the firm's governance and controls would broadly meet supervisory expectations; or

(ii) Fail to resolve the issues in a timely manner and be downgraded to a ''Deficient-1'' rating, because the firm's inability to resolve those issues would indicate that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

It is possible that a firm may be close to completing resolution of the supervisory issues leading to the ''Conditionally Meets Expectations'' rating, but new issues are identified that, taken alone, would be consistent with a ''Conditionally Meets Expectations'' rating. In this event, the firm may continue to be rated ''Conditionally Meets Expectations,'' provided the new issues do not reflect a pattern of deeper or prolonged capital planning or position weaknesses consistent with a ''Deficient'' rating.

A ''Conditionally Meets Expectations'' rating may be assigned to a firm that meets the above definition regardless of its prior rating. A firm previously rated ''Deficient'' may be upgraded to ''Conditionally Meets Expectations'' if the firm's remediation and mitigation activities are sufficiently advanced so that the firm's prospects for remaining safe and sound are no longer at significant risk, even if the firm has outstanding supervisory issues or is subject to an active enforcement action.

Deficient-1

Financial or operational deficiencies in a firm's governance and controls put the firm's prospects for remaining safe and sound through a range of conditions at significant risk. The firm is unable to remediate these deficiencies in the normal course of business, and remediation would typically require a material change to the firm's business model or financial profile, or its governance, risk management or internal control structures or practices.

Specifically, although the firm's current condition is not considered to be materially threatened, these deficiencies limit the firm's ability to align strategic business objectives with its risk appetite and risk management capabilities; maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations (including those related to consumer protection); or otherwise provide for the firm's ongoing resiliency through a range of conditions.

A ''Deficient-1'' rating may be assigned to a firm regardless of its prior rating. A firm previously rated ''Broadly Meets Expectations'' may be downgraded to ''Deficient-1'' when supervisory issues are identified that place the firm's prospects for maintaining safe-and-sound operations through a range of potentially stressful conditions at significant risk. A firm

[10] References to risk management capabilities includes risk management of business lines and independent risk management and control functions, including internal audit.

previously rated ''Conditionally Meets Expectations'' may be downgraded to ''Deficient-1'' when the firm's inability to resolve supervisory issues in a timely manner indicates that the firm does not possess sufficient financial or operational capabilities to maintain its safety and soundness through a range of conditions.

To address these financial or operational deficiencies, the firm is required to take timely corrective action to restore and maintain its governance and controls consistent with supervisory expectations. There is a strong presumption that a firm rated ''Deficient-1'' will be subject to an informal or formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-1'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. A ''Deficient-1'' rating could be a barrier for a firm seeking Federal Reserve approval of a proposal to engage in new or expansionary activities, unless the firm can demonstrate that (i) it is making meaningful, sustained progress in resolving identified deficiencies and issues; (ii) the proposed new or expansionary activities would not present a risk of exacerbating current deficiencies or issues or lead to new concerns; and (iii) the proposed activities would not distract the firm from remediating current deficiencies or issues.

Deficient-2

Financial or operational deficiencies in governance or controls present a threat to the firm's safety and soundness, or have already put the firm in an unsafe and unsound condition. Specifically, as a result of these deficiencies, the firm is unable to align strategic business objectives with its risk appetite and risk management capabilities; maintain effective and independent risk management and control functions, including internal audit; promote compliance with laws and regulations (including those related to consumer protection); or otherwise provide for the firm's ongoing resiliency.

To address these deficiencies, the firm is required to immediately (i) implement comprehensive corrective measures sufficient to restore and maintain appropriate governance and control capabilities; and (ii) demonstrate the sufficiency, credibility, and readiness of contingency planning in the event of further deterioration of the firm's financial or operational strength or resiliency. There is a strong presumption that a firm rated ''Deficient-2'' will be subject to a formal enforcement action by the Federal Reserve.

A firm rated ''Deficient-2'' for any rating component would not be considered ''well managed,'' which would subject the firm to various consequences. The Federal Reserve would be unlikely to approve any proposal from a firm rated ''Deficient-2'' to engage in new or expansionary activities.

By order of the Board of Governors of the Federal Reserve System, November 2, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–25350 Filed 11–19–18; 11:15 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2018–0782; Special Conditions No. 25–736–SC]

Special Conditions: Garmin International, Textron Aviation Inc. Model 560XL; Airplane Electronic-System Security Protection From Unauthorized Internal Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Textron Aviation Inc. (Textron) Model 560XL, formerly known as, prior to July 29, 2015, the Cessna Model 560XL. This airplane, as modified by Garmin International (Garmin), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is Garmin G5000 avionics that allow internal connection to previously isolated data networks, which are connected to systems that perform functions required for the safe operation of the airplane. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Garmin on November 21, 2018. Send comments on or before January 7, 2019.

ADDRESSES: Send comments identified by docket no. FAA–2018–0782 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, Airplane and Flightcrew Interface Section, AIR–671, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3159; email *varun.khanna@faa.gov*.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. The FAA therefore finds it unnecessary to delay the effective date and finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On March 21, 2017, Garmin applied for a supplemental type certificate to install Garmin G5000 avionics connected to the aircraft-control domain and airline information-services domain

in Textron Model 560XL airplanes. This is a twin-engine, turbofan airplane with seating for 12 passengers and two crew members, and a maximum takeoff weight of 20,200 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Garmin must show that the Textron Model 560XL airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A22CE, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Textron Model 560XL airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Textron Model 560XL airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Textron Model 560XL airplane, as modified by Garmin, will incorporate the following novel or unusual design features:

Garmin G5000 avionics that allow internal connection to previously isolated data networks, which are connected to systems that perform functions required for the safe operation of the airplane.

Discussion

The Textron Model 560XL airplane architecture is novel or unusual for commercial transport airplanes because it allows connection to previously isolated data networks connected to systems that perform functions required for the safe operation of the airplane. This data network and design integration creates a potential for unauthorized persons to access the aircraft-control domain and airline information-services domain, and presents security vulnerabilities related to the introduction of computer viruses and worms, user errors, and intentional sabotage of airplane electronic assets (networks, systems, and databases) critical to the safety and maintenance of the airplane.

The existing regulations and guidance material did not anticipate this type of system architecture or electronic access to airplane systems. Furthermore, 14 CFR regulations and the current system-safety assessment policy and techniques do not address potential security vulnerabilities, which could be exploited by unauthorized access to airplane networks and servers. Therefore, these special conditions ensure that the security of airplane systems and networks is not compromised by unauthorized wired or wireless internal access.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Textron Model 560XL airplane. Should Garmin apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A22CE to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of the features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Textron Model 560XL airplanes as modified by Garmin, for airplane electronic-system security protection from unauthorized internal access.

1. The applicant must ensure that the design provides isolation from, or airplane electronic-system security protection against, access by unauthorized sources internal to the airplane. The design must prevent inadvertent and malicious changes to, and all adverse impacts upon, airplane equipment, systems, networks, or other assets required for safe flight and operations.

2. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Des Moines, Washington, on November 15, 2018.

Chris R. Parker,

Acting Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–25363 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2018–0781; Special Conditions No. 25–737–SC]

Special Conditions: Garmin International, Textron Aviation Inc. Model 560XL; Airplane Electronic-System Security Protection From Unauthorized External Access

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Textron Aviation (Textron) Model 560XL, formerly known as, prior to July 29, 2015, the Cessna Model 560XL. This airplane, as modified by Garmin International (Garmin), will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is Garmin G5000 avionics that allow external connection to previously isolated data networks, which are connected to systems that perform

functions required for the safe operation of the airplane. This feature creates a potential for unauthorized persons to access the aircraft-control domain and airline information-services domain, and presents security vulnerabilities related to the introduction of computer viruses and worms, user errors, and intentional sabotage of airplane electronic assets (networks, systems, and databases). The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Garmin on November 21, 2018. Send comments on or before January 7, 2019.

ADDRESSES: Send comments identified by docket no. FAA–2018–0781 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Varun Khanna, Airplane and Flightcrew Interface Section, AIR–671, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, Washington 98198; telephone and fax 206–231–3159; email *varun.khanna@faa.gov*.

SUPPLEMENTARY INFORMATION: The substance of these special conditions has been published in the **Federal Register** for public comment in several prior instances with no substantive comments received. The FAA therefore finds it unnecessary to delay the effective date and finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On March 21, 2017, Garmin applied for a supplemental type certificate to install Garmin G5000 avionics connected to the aircraft-control domain and airline information-services domain in Textron Model 560XL airplanes. This is a twin-engine, turbofan airplane with seating for 12 passengers and two crew members, and a maximum takeoff weight of 20,200 pounds.

Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Garmin must show that the Textron Model 560XL airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. A22CE, or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Textron Model 560XL airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Textron Model 560XL airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.101.

Novel or Unusual Design Features

The Textron Model 560XL airplane, as modified by Garmin, will incorporate the following novel or unusual design features:

Garmin G5000 avionics that allow external connection to previously isolated data networks, which are connected to systems that perform functions required for the safe operation of the airplane.

Discussion

The Textron Model 560XL airplane architecture and network configuration may allow increased connectivity to and access from external network sources and airline operations and maintenance networks to the airplane control domain and airline information services domain. The airplane control domain and airline information-services domain perform functions required for the safe operation and maintenance of the airplane. Previously, these domains had very limited connectivity with external network sources. This data network and design integration creates a potential for unauthorized persons to access the aircraft-control domain and airline information-services domain, and presents security vulnerabilities related to the introduction of computer viruses and worms, user errors, and intentional sabotage of airplane electronic assets (networks, systems, and databases) critical to the safety and maintenance of the airplane.

The existing regulations and guidance material did not anticipate these types of airplane system architectures. Furthermore, 14 CFR regulations and the current system safety assessment policy and techniques do not address

potential security vulnerabilities, which could be exploited by unauthorized access to airplane networks, data buses, and servers. Therefore, these special conditions ensure that the security (*i.e.,* confidentiality, integrity, and availability) of airplane systems is not compromised by unauthorized wired or wireless electronic connections.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Textron Model 560XL airplane. Should Garmin apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A22CE to incorporate the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of the features on the airplane.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Textron Model 560XL airplanes, as modified by Garmin, for airplane electronic-system security protection from unauthorized external access.

1. The applicant must ensure airplane electronic-system security protection from access by unauthorized sources external to the airplane, including those possibly caused by maintenance activity.

2. The applicant must ensure that electronic-system security threats are identified and assessed, and that effective electronic-system security protection strategies are implemented to protect the airplane from all adverse impacts on safety, functionality, and continued airworthiness.

3. The applicant must establish appropriate procedures to allow the operator to ensure that continued airworthiness of the airplane is maintained, including all post-type-certification modifications that may have an impact on the approved electronic-system security safeguards.

Issued in Des Moines, Washington, on November 15, 2018.

Chris R. Parker,

Acting Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–25362 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0741; Airspace Docket No. 18–ASO–13]

RIN 2120–AA66

Amendment of Class D Airspace and Establishment of Class E Airspace; Tyndall AFB, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E surface airspace at Tyndall Air Force Base, (AFB), FL, for the safety of aircraft landing and departing the airport when the air traffic control tower is closed. Also, this action amends Class D airspace by updating the geographic coordinates of this airport, as well as replacing the outdated term ''Airport/Facility Directory'' with ''Chart Supplement''. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Effective 0901 UTC, January 3, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC, 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave, College Park, GA 30337; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E surface airspace and amends Class D airspace at Tyndall AFB, FL, to support IFR operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 45861, September 11, 2018) for Docket No. FAA–2018–0741 to establish Class E surface airspace and amend Class D airspace at Tyndall AFB, FL, to support IFR operations at this airport.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment supporting the action was received. After the comment period closed, two additional comments were received that did not clearly indicate a position in support of the proposal, or in opposition to the proposal.

Class D and E airspace designations are published in Paragraphs 5000 and 6002, respectively, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR part 71.1. The Class D and Class E

airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 establishes Class E surface airspace within a 5.4-mile radius of Tyndall AFB, FL, for the safety of aircraft landing and departing the airport when the air traffic control tower is closed.

In addition, the geographic coordinates of the airport in Class D airspace are updated to coincide with the FAA's database.

Finally, the outdated term 'Airport/Facility Directory' is replaced with 'Chart Supplement' under the Class D description.

These changes are necessary for continued safety and management of IFR operations at this airport.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, effective September 15, 2018, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Tyndall AFB, FL [Amended]

Tyndall AFB, FL
(Lat. 30°04′09″ N, long. 85°34′30″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 5.4-mile radius of Tyndall AFB. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ASO FL E2 Tyndall AFB, FL [New]

Tyndall AFB, FL
(Lat. 30°04′09″ N, long. 85°34′30″ W)

That airspace extending upward from the surface within a 5.4-mile radius of Tyndall AFB. This Class E airspace is effective during specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on November 13, 2018.

Matthew Cathcart,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2018–25328 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0745; Airspace Docket No. 18–ASO–15]

RIN 2120–AA66

Amendment of Class E Airspace, Mountain City, TN; and Establishment of Class E Airspace; Elizabethton, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace extending upward from 700 feet above the surface in Mountain City, TN, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures serving Johnson County Airport. In addition, Class E airspace extending upward from 700 feet above the surface is established in Elizabethton, TN, to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures at Elizabethton Municipal Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at these airports.

DATES: Effective 0901 UTC, January 3, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation

Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Johnson County Airport, Mountain City, TN, and establishes Class E airspace at Elizabethton Municipal, Elizabethton, TN, to support IFR operations at these airports.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 47577, September 20, 2018) for Docket No. FAA–2018–0745 to amend Class E airspace at Johnson County Airport, Mountain City, TN, and establish Class E airspace at Elizabethton Municipal, Elizabethton, TN, to support IFR operations at these airports.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 will amend Class E airspace extending upward from 700 feet or more above the surface at Johnson County Airport, Mountain City, TN, by increasing the northeast extension to 14.4 miles (from 10.9 miles), and creating a 14-mile extension southwest of the airport, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures at the airport.

Additionally, Class E airspace extending upward from 700 feet above the surface is established at Elizabethton Municipal Airport, Elizabethton, TN, within a 9.5-mile radius of the airport, and within 4-miles each side of the 243° bearing from the airport, extending from the 9.5-mile radius to 15-miles southwest of the airport to accommodate RNAV (GPS) standard instrument approach procedures for IFR operations at these airports.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO TN E5 Mountain City, TN [Amended]

Johnson County Airport, TN
(Lat. 36°25′04″ N, long. 81°49′31″ W)

That airspace extending upward from 700 feet above the surface within a 6.7 -mile radius of the Johnson County Airport, and within 3.2 miles each side of the 066° bearing from the airport, extending from the 6.7-mile radius to 14.4 miles northeast of the airport, and within 3.2 miles each side of the 251° bearing from the airport, extending from the 6.7-mile radius to 14-miles southwest of the airport.

ASO TN E5 Elizabethton, TN [New]

Elizabethton Municipal Airport, TN
(Lat. 36°22′16″ N, long. 82°10′24″ W)

That airspace extending upward from 700 feet above the surface within a 9.5-mile radius of Elizabethton Municipal Airport, and within 4-miles each side of the 243° bearing from the airport, extending from the 9.5-mile radius to 15-miles southwest of the airport.

Issued in College Park, Georgia, on November 13, 2018.

Matthew Cathcart,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2018–25329 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0825]

Drawbridge Operation Regulation; Okeechobee Waterway (Caloosahatchee River), LaBelle, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Caloosahatchee River (SR 29/LaBelle) Bridge across the Okeechobee Waterway (Caloosahatchee River), mile 103, at LaBelle, FL. The deviation is necessary to accommodate repairs to the bridge. This deviation allows the bridge single-leaf openings with advanced notice for a double-leaf opening.

DATES: This deviation is effective without actual notice from November 21, 2018 through 6 a.m. on December 31, 2018. For the purposes of enforcement, actual notice will be used from 6 a.m. on August 13, 2018, until November 21, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0825 is available at *http://www.regulations.gov*. Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email MST1 Deborah A. Schneller, Coast Guard Sector Saint Petersburg Waterways Management Division; telephone (813) 228–2194 x 8133, email *Deborah.A.Schneller@uscg.mil*.

SUPPLEMENTARY INFORMATION: Seacoast Inc., on behalf of the bridge owner, Florida Department of Transportation (FDOT), has requested a temporary deviation from the current operating regulation that governs the Caloosahatchee River (SR29/LaBelle) Bridge across the Okeechobee Waterway (Caloosahatchee River), mile 103, at LaBelle, FL. The deviation is necessary to facilitate necessary repairs to the structural integrity of the bridge. The existing bridge is a double-leaf bascule bridge with at vertical clearance in the closed to navigation position of 28 feet under normal water level conditions on the Okeechobee Waterway.

The current operating schedule is set out in 33 CFR 117.317(i)(j). Under this temporary deviation, the bridge will provide single-leaf openings utilizing the current operating schedule. Request for a double-leaf opening requires advance notice by contacting the bridge tender at (813) 228–2191 at least four hours in advance. The vertical clearance of the bridge will be reduced to 26 feet under normal water level conditions on the Okeechobee Waterway to allow for post tensioning of the existing steel floor beams. The Okeechobee Waterway (Caloosahatchee River) is used by a variety of vessels including U.S. government vessels, small commercial vessels, recreational vessels and tugs and barge traffic. The Coast Guard has carefully considered the restrictions with waterway users in publishing this temporary deviation.

Vessels able to pass through the bridge in the closed position may do so at any time. The bridge will not be able to provide a double-leaf opening for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 15, 2018.

Barry L. Dragon,

Director, Bridge Branch, Seventh Coast Guard District.

[FR Doc. 2018–25332 Filed 11–20–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0653]

RIN 1625–AA00

Safety Zone; Ohio River, Mile 28.0 to 29.2, Vanport, Pennsylvania

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Ohio River from mile 28.0 to mile 29.2. This action is necessary to protect persons, vessels, and the marine environment from potential hazards associated with power line work across the river. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: This rule is effective without actual notice from November 21, 2018 through December 31, 2018. For the purposes of enforcement, actual notice will be used from 6 a.m. on November 16, 2018 through November 21, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0653 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This safety zone must be established by November 16, 2018 and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone until after the date of the power line pulls and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest because immediate action is necessary to respond to the potential safety hazards associated with power line work, which could pose a risk to the operation and waterways users if the normal vessel traffic were to interfere with the work. Possible hazards include risks of injury or death from near or actual contact among working vessels and mariners traversing through the safety zone.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that potential hazards associated with power line pulls across the Ohio River will be a safety hazard for anyone within a 1.2 mile stretch of the Ohio River. The rule is needed to protect people from power line work which could pose a risk to the operation and waterways users if the normal vessel traffic were to interfere with the work. Possible hazards include risks of injury or death from near or actual contact among working vessels and mariners traversing through the safety zone.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 6 a.m. through 8 p.m. on November 16, 2018 through December 31, 2018. The safety zone will cover all navigable waters of the Ohio River, from mile 28.0 to mile 29.2. The duration of the zone is intended to protect persons, vessels, and the marine environment on these navigable waters before, during, and after the power line pulls. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Marine Safety Unit Pittsburgh. Persons and vessels seeking entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or by telephone at (412) 221–0807. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful instructions of the COTP or a designated representative. The COTP or a designated representative will inform the public of the enforcement period for the safety zone as well as any changes in the schedule through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 13563 (''Improving Regulation and Regulatory Review'') and 12866 (''Regulatory Planning and Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs'') directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. As this rule is not a significant regulatory action, this rule is exempt from the requirements of Executive Order 13771. See OMB's Memorandum ''Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs''' (April 5, 2017).

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian

tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 13 hours on each day that will prohibit entry on a 1.2 mile stretch of the Ohio River. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0653 to read as follows:

§ 165.T08–0653 Safety Zone; Ohio River, mile 28.0 to mile 29.2, Vanport, PA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Ohio River from mile 28.0 to mile 29.2.

(b) *Effective period.* This section is effective without actual notice from November 21, 2018 through December 31, 2018. For the purposes of enforcement, actual notice will be used from 6 a.m. on November 16, 2018 through November 21, 2018.

(c) *Enforcement periods.* This section will be enforced from 6 a.m. through 8 p.m. daily. Breaks in the power line work will occur during the enforcement periods, which will allow for vessels to pass through the safety zone. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) or a designated representative will provide notice of breaks as appropriate under paragraph (e) of this section.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into this zone is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Marine Safety Unit Pittsburgh.

(2) Persons and vessels seeking entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or by telephone at (412) 221–0807.

(3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful instructions of the COTP or a designated representative.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement period for the safety zone as well as any changes in the schedule through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: November 16, 2018.

A.W. Demo,

Commander, U.S. Coast Guard, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2018–25379 Filed 11–20–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2017–0056; 4500030113]

RIN 1018–BC44

Endangered and Threatened Wildlife and Plants; Endangered Species Status for the Candy Darter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine endangered species status under the Endangered Species Act of 1973 (Act), as amended, for the candy darter (*Etheostoma osburni*), a freshwater fish species from Virginia and West Virginia. This rule adds this species to the Federal List of Endangered and Threatened Wildlife.

DATES: This rule is effective December 21, 2018.

ADDRESSES: This final rule is available on the internet at *http://www.regulations.gov* and *https://www.fws.gov/northeast/candydarter*. Comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov*. Comments, materials, and documentation that we considered in this rulemaking will be available by appointment, during normal business hours, at: U.S. Fish and Wildlife Service, West Virginia Ecological Services Field Office, 694 Beverly Pike, Elkins, WV 26241–9475; telephone 304–636–6586.

FOR FURTHER INFORMATION CONTACT: John Schmidt, Field Supervisor, West Virginia Ecological Services Field Office, 694 Beverly Pike, Elkins, WV 26241–9475; telephone 304–636–6586. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Previous Federal Actions

Please refer to our October 4, 2017, proposed rule (82 FR 46197) for a detailed description of previous Federal actions concerning the candy darter. Elsewhere in today's **Federal Register**, we propose the designation of critical habitat for the candy darter; that proposal also discusses our intent to reestablish populations within the candy darter's historical range under section 10(j) of the Act in a future publication. And we are seeking public input on other potential recovery tools (*e.g.,* safe harbor agreements), through the proposed critical habitat designation public comment period.

Background

Please refer to our October 4, 2017, proposed rule (82 FR 46197) for a summary of species information available to the Service at the time that it was published. Based on information we received during the proposed rule's public comment period, we updated the current condition discussion in the species status assessment (SSA) report to more accurately reflect the current spread level of hybridization, which is the primary threat to the species, in the candy darter's range (Service 2018). The candy darter's current condition is more degraded than we understood when we published the October 4, 2017, proposed listing rule. Consequently, because the species' current condition (*i.e.,* the baseline or starting point for the SSA's future scenario projections) is more degraded, the species' future condition is also likely to be further degraded than we had previously estimated. With this more accurate reflection of the candy darter's current condition, the risk of extinction is greater than we had previously understood, and we have determined that the species does not meet the definition of a threatened species (as proposed). We find that endangered is the appropriate status for the candy darter (see Determination, below).

We also received information during the public comment period that demonstrates a stronger genetic separation between candy darters in the Greenbrier watershed and the Gauley watershed. All the information was incorporated into an updated version of the SSA report, which is available online at *https://www.fws.gov/northeast/candydarter*.

Summary of Biological Status and Threats

The Act directs us to determine whether any species is an endangered species or a threatened species because of any factors affecting its continued existence. We completed a comprehensive assessment of the biological status of the candy darter and prepared a report of the assessment (SSA report), which provides a thorough account of the species' overall viability using the conservation biology principles of resiliency, redundancy, and representation (collectively, the ''3Rs''). We have used the SSA report's assessment of the candy darter's current and potential future status, based on the factors influencing the species, framed in the context of the 3Rs, and information provided during the public comment period on the October 4, 2017, proposed listing rule to inform our determination of whether the candy darter meets the definition of an endangered or a threatened species (see Determination, below).

Because we have included information below about the candy darter's 3Rs, we further define those terms here. Resiliency means having sufficiently large populations for the species to withstand stochastic events (arising from random factors). We can measure resiliency based on metrics of population health; for example, birth versus death rates and population size, if that information exists. Resilient populations are better able to withstand disturbances such as random fluctuations in birth rates (demographic stochasticity), variations in rainfall (environmental stochasticity), or the effects of human activities. Redundancy means having a sufficient number of populations for the species to withstand catastrophic events (such as a rare destructive natural event or episode involving many populations). Redundancy is about spreading the risk and can be measured through the duplication and distribution of populations across the range of the species. Generally, the greater the number of populations a species has distributed over a larger landscape, the better it can withstand catastrophic events. Representation means having the breadth of genetic makeup for the species to adapt to changing environmental conditions. Representation can be measured through the genetic diversity within and among populations and the ecological diversity (also called environmental variation or diversity) of populations across the species' range. The more representation, or diversity, a species has, the more it is capable of adapting to changes (natural or human caused) in its environment.

In the absence of species-specific genetic and ecological diversity information, we evaluate representation based on the extent and variability of habitat characteristics within the geographical range. We define viability here as the ability of the species to persist in the wild over time and, conversely, to avoid extinction.

Below, we summarize the conclusions of the candy darter's SSA analysis (Service 2018, entire), which can be accessed at Docket FWS–R5–ES–2017–0056 on *http://www.regulations.gov* and at *https://www.fws.gov/northeast/candydarter*. The SSA report documents the results of our comprehensive biological status review for the candy darter, including an assessment of the factors influencing its continued existence. The SSA report does not represent a decision by the Service on whether the candy darter should be listed as an endangered or a threatened species under the Act. Rather, the SSA report provides the scientific basis that informs our regulatory decision, which involves the further application of standards within the Act and its implementing regulations and policies. The Act directs us to determine whether any species is an endangered species or a threatened species (*i.e.,* whether it meets the definition of a threatened or endangered species) because of any factors affecting its continued existence. Below, we review the biological condition of the species and its resources and the factors influencing the species and resources to assess the species' overall viability and the risks to that viability.

Summary of Current Condition

Historically, the candy darter consisted 35 populations in Virginia and West Virginia distributed across 7 metapopulations in the Bluestone, Lower New River, Upper Gauley, Lower Gauley, and Middle New watersheds in the Appalachian Plateaus physiographic province and the Upper New River and Greenbrier watersheds in the Valley and Ridge physiographic province. See Chapter 3 of the SSA report for more details (Service 2018, pp. 30–31).

Within these two physiographic provinces, the candy darter has been extirpated from almost half of its historical range (17 of 35 (49 percent) known populations, and 2 of 7 (29 percent) known metapopulations), with the extirpations representing a complete loss of resiliency in those populations (or metapopulations). We qualitatively assessed the remaining (extant) populations, placing them in ''low,'' ''moderate,'' or ''high'' categories that represent the populations' potential to rebound after stochastic events. These categories were based on a combination of eight physical habitat, nonnative

competition, and candy darter demographic metrics (see Service 2018, pp. 51, 84–102). Of the 18 extant populations, 5 (28 percent) have a current score of high or moderate to high resiliency, 9 (50 percent) have moderate resiliency, and 4 (22 percent) have low or moderate to low resiliency (see table 4 in the SSA report (Service 2018, p, 46). The five populations with higher resiliency constitute three metapopulations (the Upper Gauley in the Appalachian Plateaus physiographic province and the Greenbrier and Middle New in the Valley and Ridge physiographic province); the remaining two extant metapopulations (the Lower Gauley in the Appalachian Plateaus physiographic province and the Upper New River in the Valley and Ridge physiographic province) maintain populations with moderate and low resiliency. Therefore, we conclude the candy darter's populations currently have moderate resiliency because the four out of the five metapopulations have moderate to high resiliency.

This loss of these candy darter populations, which represent the species' genetic, ecological, and niche diversity within its historical range, as well as the fragmentation of extant populations, has compromised the species' ability to repatriate those areas or avoid species-level effects of a catastrophic event. Based on the species' distribution and condition within each of the seven historical metapopulations (one with moderate to high internal redundancy, one with moderate internal redundancy, one with low internal redundancy, two with no internal redundancy, and two that have been extirpated), we conclude, based on the best available data, that the candy darter's current redundancy is low (Service 2018, pp. 26–28, 49–50).

While the candy darter currently maintains representation in both the Appalachian Plateaus and Valley and Ridge physiographic provinces, only a single metapopulation in each province has a moderate to high resiliency score. As related to the species' occupation in a diversity of environmental settings, candy darters have lost representation from lower mainstem rivers and tributaries. While researchers have noted differences in the genetic, physical, behavioral, or developmental characteristics of some stream fish species based on the species' longitudinal position in the watershed (*e.g.,* stream size) (Neville *et al.* 2006, pp. 911–913), but we have no data indicating candy darters exhibit similar differences based on their particular environmental setting. Although the candy darter retains representation in both the Appalachian Plateaus and Valley and Ridge physiographic provinces, the species has a reduced distribution than it had historically and likely a reduced ability to respond to stochastic and catastrophic events, thereby putting the species at increased risk of extinction from any such events (Service 2018, pp. 50–51). The available genetic data for the candy darter indicate that the Upper and Lower Gauley River metapopulations are different from the Greenbrier metapopulation. While we have no information regarding the evolutionary significance of these genetic differences to either metapopulation, the loss of either metapopulation would represent a loss to the species' genetic diversity. Therefore, we conclude that the species' representation is currently moderate to low (Service 2018, pp. 26–29, 50–51).

The candy darter is currently distributed in five of the historical seven metapopulations. The populations within those metapopulations generally have moderate to low resiliency and redundancy scores. While the candy darter is present in the two physiographic provinces from which it is historically known, the species is not found in lower mainstem rivers and tributaries in which it once existed (Service 2018, Chapter 3). This fact leads us to conclude the candy darter's representation is also moderate to low. Therefore, our analysis under the 3Rs leads us to conclude that the current condition of the candy darter is currently moderate to low.

Risk Factors for the Candy Darter

Based on the candy darter's life history and habitat needs, and in consultation with species' experts from Virginia and West Virginia State and Federal agencies and academic institutions, we identified the potential stressors (negative influences), the contributing sources of those stressors, and conservation measures to address those stressors that are likely to affect the species' current condition and viability (Service 2018, pp. 32–43). We evaluated how these stressors may be currently affecting the species and whether, and to what extent, they would affect the species in the future (Service 2018, pp. 52–66). Water temperature, excessive sedimentation, habitat fragmentation, water chemistry, water flow, and nonnative competition likely influenced the species in the past and contributed to its current condition, and may continue to affect some populations in the future (Service 2018, pp. 44, 46, 52–67). However, habitat stressors are not considered to be a primary source of risk to candy darter viability in the future. Hybridization with the closely related variegate darter (*Etheostoma variatum*) appears to be having, and will continue to have, the greatest influence on candy darter populations and the candy darter's overall viability within the next 25 years (Service 2018, pp. 52–66). While we acknowledge there is uncertainty regarding some of the scientific data and assumptions used to assess the biological condition of the candy darter, the species' experts generally agreed with the overall methodology for assessing the candy darter's current and projected future condition, and confirmed that the results were reflective of their observations of the candy darter and its habitat.

As mentioned above, the primary stressor to the candy darter is hybridization with the variegate darter (Service 2018, pp. 32–37), a species that is native to the Kanawha River basin below the Kanawha Falls in Fayette County, West Virginia. The Kanawha Falls serve as a natural barrier to fish dispersal from the lower Kanawha River basin (and greater Ohio River basin) upstream into the range of the candy darter in the upper Kanawha River basin. However, in the late 20th century, the variegate darter was introduced, likely by ''bait bucket transfer,'' into the upper Kanawha basin. Since they were first observed in the upper Kanawha basin in 1982 and 2002, variegate darters have expanded their range approximately 3 to 9 stream miles per year over the course of the last 20 or more years within the range of the candy darter. Genetic studies have demonstrated that where variegate and candy darter ranges now overlap, the two species will hybridize, and consistent, repeated contact will quickly result in ''genetic swamping'' (the homogenization or replacement of native genotypes) of the endemic candy darter population and eventually its complete replacement by variegate darters or hybrids (Service 2018, pp. 32–37).

Summary of Future Conditions Analysis

We modeled five scenarios to assess the potential viability of the candy darter at a point up to 25 years in the future (Service 2018, pp. 52–66). Two scenarios were focused on habitat change (one positive and the other negative), and three scenarios were focused on variegate darter invasion. However, the habitat change scenarios, by themselves, are not plausible scenarios because variegate darter hybridization is ongoing and highly likely to continue (see chapter 4 and appendix B of the SSA report for

additional information). We chose to model all scenarios out to 25 years because we have data to reasonably predict potential habitat and variegate darter changes and their effects on the candy darter within this timeframe.

Under the three most plausible scenarios, those that include the variegate darter invasion, the predicted rate of variegate darter expansion and hybridization remains the same, and at the end of 25 years, the candy darter will likely occur in four isolated populations and maintain little resilience, redundancy, or representation. The effects of significant positive or negative habitat changes do not alter this outcome; however, because variegate darters may be more tolerant of a wider range of habitat conditions, negative habitat changes could selectively benefit variegate darters and increase the rate at which candy darters are extirpated (Service 2018, p. 64).

The candy darter SSA report (Service 2018, entire) contains a more detailed discussion of our evaluation of the biological status of the candy darter and the influences that may affect its continued existence. Our conclusions are based upon the best available scientific and commercial data, including the expert opinion of the species' experts (fishery biologists, aquatic ecologists, and geneticists from State and Federal agencies and academic institutions) and the SSA team members. Please see the SSA report for a complete list of the species experts and peer reviewers and their affiliations.

Summary of Changes From the Proposed Rule

We received information during the public comment period that concluded we had inaccurately described the current condition of some populations of the candy darter. The current condition of the candy darter populations in five streams in the Upper Gauley watershed is more degraded than we had understood when we proposed the candy darter for listing. We inaccurately stated that ''[v]ariegate darters have not yet been detected in the remainder of the candy darter's range (*i.e.,* the Upper Gauley watershed in West Virginia.'' Based on comments we received regarding the spread of the variegate darter in the upper Gauley drainage, the risk of hybridization appears imminent and may already be widespread (see Summary of Comments and Recommendations, below). We incorporated this information into an updated version of the SSA report (Service 2018). The risk of extinction is higher (see Determination, below) than we characterized in the proposal to list the candy darter as a threatened species (82 FR 46197; October 4, 2017).

Additionally, we received information during the public comment period that demonstrated that there is greater genetic differentiation between candy darter in the Greenbrier watershed and candy darter in the Gauley watershed (see Summary of Comments and Recommendations, below). We incorporated this information into an updated version of the SSA report (Service 2018).

We reassessed our analysis (after reviewing all public comments), updated the SSA report, and, after evaluating the best available information and the Act's regulation and policies, determined that the candy darter meets the definition of an endangered species, and such designation is more appropriate than that of a threatened species as originally proposed.

Summary of Comments and Recommendations

In the proposed rule published on October 4, 2017 (82 FR 46197), we requested that all interested parties submit written comments on the proposal by December 4, 2017. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. A newspaper notification inviting general public comment was published in the USA Today on October 10, 2017. We did not receive any requests for a public hearing. All substantive information provided during the comment period has either been incorporated directly into this final determination or is addressed below, as appropriate.

Peer Reviewer Comments

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270) and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of six individuals (and received responses from four) with expertise in darters; fisheries, population, or landscape ecology; genetics and conservation genetics; and/or speciation and conservation biology regarding the SSA report (Service 2018). The purpose of peer review is to ensure that our designation is based on scientifically sound data, assumptions, and analyses. The peer reviewers generally concurred with our methods and conclusions and provided additional information, clarifications, and suggestions to improve the final SSA report. The SSA report and peer reviews can be found on *http://www.regulations.gov* under Docket No. FWS–R5–ES–2017–0056. The SSA report informed the proposed rule (82 FR 46197; October 4, 2017) and this final rule.

Comments From States

(1) Comment: The West Virginia Division of Natural Resources (WVDNR) and one public commenter stated that given the fact that variegate darter alleles were detected in the Upper Gauley in 2014 the spread of hybrids in the Upper Gauley drainage appears imminent and may already be widespread based on the rapid spread of hybrids in the Greenbrier drainage.

Our Response: After reviewing how we assessed the hybridization metric, one of eight metrics in our candy darter condition model, we concluded that we had previously underestimated the risk of hybridization in the Upper Gauley. Therefore, we have updated the analysis in the SSA report to address this concern. This information was the primary reason we changed our determination from threatened to endangered.

(2) Comment: The WVDNR stated that the Gauley and Greenbrier river populations of candy darter have a high level of genetic differentiation that borders on species-level differentiation. The Greenbrier River population appears to be on a definite ''trajectory to extinction.'' Loss of candy darter in the Greenbrier river would drastically reduce genetic diversity of the species and leave the Gauley River and Virginia populations separated by substantial geographic distance and two physical barriers (*i.e.,* Summersville and Bluestone dams).

Our Response: The best available genetic information suggests genetic differences exist between these watersheds. We have updated the SSA report to reflect the importance of these genetic differences.

Public Comments

(3) Comment: One commenter provided additional supporting evidence of the genetic differentiation between the Greenbrier and Gauley metapopulations.

Our Response: We incorporated the information into our SSA report.

(4) Comment: One commenter believed that the candy darter has been extirpated from 77.2 its range rather than 49 percent, as we stated in the proposed rule. They also stated that the situation is likely worse than that

because three of the four populations in the Upper Gauley that are labeled as ''extant candy darter populations'' have not been genetically analyzed; if they were genetically analyzed, they may fall into the category of ''extant candy darter population with variegate darter alleles.''

Our Response: This final determination relies on the best scientific information available. At this time, we do not have genetic information (or evidence otherwise) to fully evaluate the genetics of the populations in the Gauley; therefore, we do not assume they are candy darter with variegate darter alleles. We we recognize uncertainty in the data and that the situation may be worse than we are aware.

(5) Comment: Three commenters recommended exemptions for activities for the Service to consider in the event that we drafted a species-specific rule under section 4(d) of the Act (''4(d) rule'').

Our Response: The Service has determined that the candy darter meets the definition of an endangered species, and the Act does not allow for the promulgation of a 4(d) rule when a species is listed as endangered.

Determination

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the candy darter. Our analysis of this information indicates that, at the species level, hybridization with variegate darters (Factor E) is the most influential factor affecting the candy darter now and into the future. Excessive sedimentation and increased water temperatures degraded once-suitable habitat (Factor A) and likely caused historical declines of the candy darter. We also analyzed existing regulatory mechanisms (such as the Federal Clean Water Act of 1977 (33 U.S.C. 1251 *et seq.*), Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1234–1328), West Virginia Water Pollution Control Act (WVSC § 22–11) and the increased implementation of forestry and construction ''best management practices'' designed to reduce erosion and sedimentation) (Factor D) to reduce or eliminate sedimentation and found that these mechanisms were not sufficient to protect the species from extinction as excessive sedimentation and increased water temperatures continue to affect some of the remaining populations. There may be additional infrastructure projects (*e.g.,* roads, pipeline, etc.) that increase sediment loading within the range of the candy darter as a result of stream crossings or forest clearing for permanent rights of way. Additionally, the current level of habitat fragmentation (Factor A) isolates some populations, which reduces gene flow and limits the potential for the species to colonize or recolonize streams if habitat conditions change. Other factors such as flow alterations and water quality degradation that affect habitat (Factor A), and the stocking of nonnative species that can eat (Factor C) or outcompete (Factor E) the candy darter are not expected to cause species-level effects. In addition, we have no evidence that overutilization (Factor B) or disease (Factor C) is affecting individuals or populations of candy darters.

Active hybridization with variegate darters has occurred or is currently occurring in multiple streams within the Lower New, Lower Gauley, and Greenbrier River watersheds in West Virginia (Service 2018, p. 37). Although variegate darter individuals have not yet been detected in the remainder of the candy darter's range (*i.e.,* the Middle New and Upper New watersheds in Virginia), variegate darter alleles have been detected in two separate locations in the Upper Gauley watershed, indicating that hybridization occurred at one time and currently likely underway. Additionally, the risk is moderately high that variegate darter introductions will continue to occur in these watersheds because if watersheds occupied by variegate darters (and hybrids) are adjacent to candy darter watersheds, the likelihood that variegate darters will be collected as bait and transported into an adjacent candy darter watershed is increased. When this happens, variegate darters ultimately replace most candy darter populations throughout the candy darter's range. The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range.'' We find that an endangered species status is appropriate for the candy darter because the species is facing a catastrophic threat from which the risk of extinction is imminent and certain. The introduction of variegate darters is occurring, and the consequence that it will extirpate any local candy darter population that variegate darters come into sustained contact with is imminent and certain across the species' remaining range. As a result of their limited range and/or population size, narrowly endemic species are inherently vulnerable to extinction when subject to elevated threats. The candy darter has a moderately small range, which has only become more restricted, as 77 percent (27 of 35 populations (see SSA report, table 4)) of its range has been lost through historical land use changes and/or has been invaded by the variegate darter. Therefore, we conclude that the current risk of extinction of the candy darter is such that it does not meet the definition of a threatened species under the Act.

The Act defines an endangered species as any species that is ''in danger of extinction throughout all or a significant portion of its range'' and a threatened species as any species ''that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future.'' We find that the candy darter is presently in danger of extinction throughout its entire range based on the severity and immediacy of threats currently affecting the species. The overall range has been significantly reduced, and the remaining populations are threatened by hybridization and, to a lesser extent, a combination of other threats, reducing the overall viability of the species. The risk of extinction is high because the remaining populations are isolated and the threat of hybridization is ongoing and increasing. Therefore, on the basis of the best available scientific and commercial data, we are listing the candy darter as endangered in accordance with sections 3(6) and 4(a)(1) of the Act. We find that a threatened species status is not appropriate for the candy darter because of the reasons previously outlined and because the threats, which occur throughout the species' range, are expected to continue to increase, putting the species at risk of extinction now.

Under the Act and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. Because we have determined that the candy darter is in danger of extinction throughout its range, we find it unnecessary to proceed to an

evaluation of potentially significant portions of the range. Where the best available information allows the Services to determine a status for the species rangewide, that determination should be given conclusive weight because a rangewide determination of status more accurately reflects the species' degree of imperilment and better promotes the purposes of the statute. Under this reading, we should first consider whether listing is appropriate based on a rangewide analysis and proceed to conduct a ''significant portion of its range'' analysis if, and only if, a species does not qualify for listing as either endangered or threatened according to the ''all'' language. We note that the court in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), did not address this issue, and our conclusion is therefore consistent with the opinion in that case.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, state, Tribal, and local agencies; private organizations; and individuals. The Act encourages cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Subsection 4(f) of the Act requires the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning includes the development of a recovery outline shortly after a species is listed and preparation of a draft and final recovery plan. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. As part of our conservation strategy for the candy darter, which will inform the forthcoming recovery outline and informs the proposed critical habitat rule published elsewhere in today's **Federal Register**, we identified the need to reestablish candy darter populations within areas of its historical range. Because the candy darter is extirpated from some areas and natural repopulation is not possible without human assistance, use of a 10(j) rule under the Act may be one appropriate tool to achieve this recovery objective. An overview of the process to establish an experimental population under section 10(j) of the Act is described in detail in the proposed critical habitat rule published elsewhere in today's **Federal Register**. In addition to using the authorities under 10(j) of the Act in areas not currently occupied by the candy darter, the condition of existing candy darter populations may be improved by working with non-Federal landowners through safe harbor agreements, authorized under section 10(a)(1)(A) of the Act. More information about safe harbor agreements can be found online at: *https://www.fws.gov/endangered/landowners/safe-harbor-agreements.html*. We intend to fully explore all of the appropriate recovery tools for the candy darter with our State, Federal, non-governmental, and private partners.

The recovery plan identifies site-specific management actions that set a trigger for review of whether a species remains endangered or may be reclassified from endangered to threatened (''downlisted'') or removed from the Lists of Endangered and Threatened Wildlife and Plants (''delisted''), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (*http://www.fws.gov/endangered*) or from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, states, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (*e.g.,* restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. Achieving recovery of these species requires cooperative conservation efforts on private, state, and Tribal lands.

Following publication of this final listing rule, funding for recovery actions will be available from a variety of sources, including Federal budgets, state programs, and cost share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Virginia and West Virginia will be eligible for Federal funds to implement management actions that promote the recovery of the candy darter. Information on our grant programs that are available to aid species recovery can be found at: *http://www.fws.gov/grants*.

Please let us know if you are interested in participating in recovery efforts for the candy darter. Additionally, we invite you to submit any new information on this species whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of any endangered or threatened species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the species' habitat that may require consultation as described in the preceding paragraph include, but are not limited to, management (*e.g.,* captive propagation) and any other landscape-altering activities on Federal lands administered by the U.S. Forest Service (Monongahela and the George Washington and Jefferson National

Forests) and the National Park Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; and construction and maintenance of roads or highways by the Federal Highway Administration.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to endangered wildlife. The prohibitions of section 9(a)(1) of the Act, codified at 50 CFR 17.21, make it illegal for any person subject to the jurisdiction of the United States to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these) endangered wildlife within the United States or on the high seas. In addition, it is unlawful to import; export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to employees of the Service, the National Marine Fisheries Service, other Federal land management agencies, and State conservation agencies.

We may issue permits to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. With regard to endangered wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a final listing on proposed and ongoing activities within the range of a listed species. Based on the best available information, the following actions are unlikely to result in a violation of section 9, if these activities are carried out in accordance with existing regulations and permit requirements; this list is not comprehensive:

- Normal agricultural practices, including herbicide and pesticide use, carried out in accordance with any existing regulations and with permit and label requirements.

Based on the best available information, the following activities may potentially result in a violation of section 9 the Act; this list is not comprehensive:

(1) Introduction of variegate darters into suitable candy darter habitat;

(2) Stocking of nonnative species into suitable candy darter habitat;

(3) Destruction or alteration of the habitat of the candy darter (*e.g.,* unpermitted instream dredging, impoundment, water diversion or withdrawal, channelization, discharge of fill material) that impairs essential behaviors such as breeding, feeding, or sheltering, or results in killing or injuring a candy darter; and

(4) Discharges or dumping of toxic chemicals or other pollutants into waters supporting the candy darter that kills or injures individuals, or otherwise impairs essential life-sustaining behaviors such as breeding, feeding, or finding shelter.

Questions regarding whether specific activities would constitute a violation of section 9 of the Act should be directed, as follows:

- In West Virginia, to the West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**); or
- In Virginia, to the Southwestern Virginia Field Office (330 Cummings Street, Abingdon, VA 24210–3208; telephone 276–623–1233).

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. The candy darter does not occur on federally recognized Tribal or Tribal interest lands.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* and upon request from the West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this final rule are the staff members of the Services' Species Assessment Team, the West Virginia Ecological Services Field Office, and the Southwestern Virginia Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.11(h) by adding, in alphabetical order under FISHES, an entry for ''Darter, candy'' to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	* * *
Fishes				
*	*	*	*	* * *
Darter, candy	*Etheostoma osburni*	Wherever found	E	83 FR [insert **Federal Register** page where the document begins], 11/21/2018.
*	*	*	*	* * *

* * * * *

Dated: September 6, 2018.

James W. Kurth,

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–25316 Filed 11–20–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG639

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher/Processors Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting retention of Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary because the 2018 Pacific cod apportionment for catcher/processors using trawl gear in the Central Regulatory Area of the GOA has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 19, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 Pacific cod apportionment for catcher/processors using trawl gear in the Central Regulatory Area of the GOA is 253 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS, has determined that the 2018 Pacific cod apportionment for catcher/processors using trawl gear in the Central Regulatory Area of the GOA will be reached. Therefore, NMFS is requiring that Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 679.21(b).

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay prohibiting the retention of Pacific cod by catcher/processors using trawl gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 15, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and § 679.21 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 16, 2018.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–25399 Filed 11–16–18; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 83, No. 225
Wednesday, November 21, 2018

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

Notice of Public Meeting of the Assembly of the Administrative Conference of the United States

AGENCY: Administrative Conference of the United States.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Assembly of the Administrative Conference of the United States will hold a meeting to consider five proposed recommendations and to conduct other business. This meeting will be open to the public.

DATES: The meeting will take place on Thursday, December 13, 2018, 1:00 p.m. to 5:15 p.m., and Friday, December 14, 2018, 9:00 a.m. to 11:45 a.m. The meeting may adjourn early if all business is finished.

ADDRESSES: The meeting will be held at the George Washington University Law School, Jacob Burns Moot Court Room, 2000 H Street NW, Washington, DC 20052.

FOR FURTHER INFORMATION CONTACT: Shawne McGibbon, General Counsel (Designated Federal Officer), Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036; Telephone 202–480–2080; email *smcgibbon@acus.gov*.

SUPPLEMENTARY INFORMATION: The Administrative Conference of the United States makes recommendations to federal agencies, the President, Congress, and the Judicial Conference of the United States regarding the improvement of administrative procedures (5 U.S.C. 594). The membership of the Conference, when meeting in plenary session, constitutes the Assembly of the Conference (5 U.S.C. 595).

Agenda: The Assembly will consider five proposed recommendations as described below:

Recusal Rules for Administrative Adjudicators. This proposed recommendation urges agencies to adopt procedural regulations governing the recusal of adjudicators—as distinct from the ethics laws and regulations generally applicable to all federal employees—and provides guidance on how such regulations should be promulgated and enforced. The proposed recommendation expands upon ACUS Recommendation 2016–4, *Evidentiary Hearings Not Required by the Administrative Procedure Act,* and revisits parts of the recommendation proposed by the Committee on Adjudication entitled *Administrative Judges*. Unlike these earlier recommendations, the proposed recommendation covers both administrative law judges (ALJs) and non-ALJ adjudicators.

Public Availability of Adjudication Rules. This proposed recommendation offers best practices to agencies for enhancing the accessibility of the procedural rules that govern the adjudications they conduct. Among other things, it encourages agencies to make procedural rules for adjudications and related guidance documents available on their websites and to organize those materials in a way that allows both parties appearing before the agencies and members of the public to easily access the documents and understand their legal significance.

Regulations.gov and the Federal Docket Management System (FDMS). This proposed recommendation offers suggested improvements to *Regulations.gov*, the website that allows the public to comment on many federal agencies' rulemaking proposals. It provides recommendations to the governing body of *Regulations.gov*, called the eRulemaking Program, and to agencies that participate in *Regulations.gov* for ensuring that rulemaking materials on *Regulations.gov* are easily searchable and categorized consistently and clearly.

Public Engagement in Rulemaking. This proposed recommendation offers strategies for agencies to enhance public engagement prior to and during informal rulemaking. It encourages agencies to invest resources in a way that maximizes the probability that rule-writers obtain high quality public information as early in the process as possible. It recommends expanding the use of requests for information and advance notices of proposed rulemaking, targeting outreach to reach individuals who might otherwise be unlikely to participate, and taking advantage of in-person engagement opportunities to solicit stakeholder input and support future informed participation.

Public-Private Partnerships. This proposed recommendation offers agencies guidance on legal and other considerations for participating in public-private partnerships. It commends to agencies a *Guide to Legal Issues Encountered in Public-Private Partnerships,* published by an interagency working group convened by the Office of the Chairman of the Administrative Conference, and proposes mechanisms that allow agencies to share resources and best practices with one another for purposes of creating and maintaining public-private partnerships.

Additional information about the proposed recommendations and the order of the agenda, as well as other materials related to the meeting, can be found at the 70th Plenary Session page on the Conference's website: *https://www.acus.gov/meetings-and-events/plenary-meeting/70th-plenary-session*.

Public Participation: The Conference welcomes the attendance of the public at the meeting, subject to space limitations, and will make every effort to accommodate persons with disabilities or special needs. Members of the public who wish to attend in person are asked to RSVP online at the 70th Plenary Session web page shown above, no later than two days before the meeting, in order to facilitate entry. Members of the public who attend the meeting may be permitted to speak only with the consent of the Chairman and the unanimous approval of the members of the Assembly. If you need special accommodations due to disability, please inform the Designated Federal Officer noted above at least 7 days in advance of the meeting. The public may also view the meeting through a live webcast, which will be available at *https://www.youtube.com/user/gwlawschool* during the course of the event. At the conclusion of the event,

the webcast will be archived and available for later viewing on the 70th Plenary Session web page.

Written Comments: Persons who wish to comment on any of the proposed recommendations may do so by submitting a written statement either online by clicking ''Submit a Comment'' on the 70th Plenary Session web page shown above or by mail addressed to: December 2018 Plenary Session Comments, Administrative Conference of the United States, Suite 706 South, 1120 20th Street NW, Washington, DC 20036. Written submissions must be received no later than 10:00 a.m. (EDT), Friday, December 7, 2018, to assure consideration by the Assembly.

Dated: November 16, 2018.

Shawne McGibbon,

General Counsel.

[FR Doc. 2018–25401 Filed 11–20–18; 8:45 am]

BILLING CODE 6110–01–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 16, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 21, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725-17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Notice of Request for a New Information Collection: (Consumer Research on the Safe Handling Instructions Label for Raw and Partially Cooked Meat and Poultry Products and Labeling Statements for Ready-to-Eat and Not-Ready-to-Eat Products).

OMB Control Number: 0583-New.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031). These statues mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

Need and Use of the Information: FSIS is announcing its intention to collect information in the form of consumer research that will include a web-based experimental study and a behavior change study to help inform potential revisions to the current Safe Handling Instructions (SHI) label and assess whether a label revision would improve consumer food safety behaviors. FSIS also will collect information on consumer use and understanding of the labeling on ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products, in particular consumers' ability to discern between the two types of products and to ensure that NRTE products that may appear to be ready to eat are thoroughly cooked.

Description of Respondents: Individuals or households.

Number of Respondents: 73,395.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 5,115.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–25395 Filed 11–20–18; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 16, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 21, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Institute of Food and Agriculture

Title: Organizational Information.

OMB Control Number: 0524–0026.

Summary of Collection: The National Institute of Food and Agriculture (NIFA) has primary responsibility for providing linkages between the Federal and State components of a broad-based, national agricultural research, extension, and higher education system. Focused on national issues, its purpose is to represent the Secretary of Agriculture and the intent of Congress by administering formula and grant funds appropriated for agricultural research, extension, and higher education. Before awards can be made, certain information is required from applicant to effectively assess the potential recipient's capacity to manage Federal funds. NIFA will collection information using form NIFA 666, ''Organizational Information.''

Need and Use of the Information: NIFA will collect information to determine that applicants recommended for awards will be responsible recipients of Federal funds. The information pertains to organizational management and financial matters of the potential grantee. If the information were not collected, it would not be possible to determine that the prospective grantees are responsible.

Description of Respondents: Not-for-profit institutions; Business or other for-profit; Individuals or households; State, Local, or Tribal Government; Federal Government.

Number of Respondents: 150.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 945.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2018–25403 Filed 11–20–18; 8:45 am]

BILLING CODE 3410–09–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: 10 a.m. CST, December 12, 2018.

PLACE: University of Wisconsin—Superior, Yellowjacket Union located at Belknap and Union Ave.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Chemical Safety and Hazard Investigation Board (CSB) will convene a public town hall meeting on Wednesday December 12, 2018, starting at 10:00 a.m. CST in the Yellowjacket Union located at Belknap and Union Ave at the University of Wisconsin—Superior. CSB investigative staff will present a factual update on the Husky Refinery fire which occurred on April 28, 2018. Staff presentations are preliminary and are intended to allow the Board to consider in a public forum the issues and factors involved in this case. The Board will provide an opportunity for public comment.

Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the **CONTACT PERSON FOR FURTHER INFORMATION**, at least three business days prior to the meeting.

The CSB is an independent Federal agency charged with investigating accidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

The time provided for public statements will depend upon the number of people who wish to speak. The public comments will be directed towards the board and facilitated by the Interim Executive. Speakers should assume that their presentations will be limited to three minutes or less, but commenters may submit written statements for the record.

CONTACT PERSON FOR MORE INFORMATION: Hillary Cohen, Communication Manager, at *public@csb.gov* or (202) 446–8094. Further information about the CSB and this public meeting can be found on the CSB website at: *www.csb.gov*.

Dated: November 19, 2018.

Raymond Porfiri,

Deputy General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2018–25534 Filed 11–19–18; 4:15 pm]

BILLING CODE 6350–01–P

CIVIL RIGHTS COMMISSION

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission Telephonic Business Meeting.

DATES: Tuesday, November 27, 2018, at 11:00 a.m. ET.

ADDRESSES: Meeting to take place by telephone.

FOR FURTHER INFORMATION CONTACT: Brian Walch, (202) 376–8371, *publicaffairs@usccr.gov*.

SUPPLEMENTARY INFORMATION: This business meeting is open to the public by telephone only.

Participant Access Instructions: Public call-in information will be available in advance of the meeting at *www.usccr.gov, https://twitter.com/USCCRgov* and *https://www.facebook.com/USCCRgov/*.

Meeting Agenda

I. Approval of Agenda
II. Discussion of Discovery Plan
III. Adjourn Meeting.

Dated: November 19, 2018.

Brian Walch,

Director, Communications and Public Engagement.

[FR Doc. 2018–25588 Filed 11–19–18; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–489–825]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From the Republic of Turkey: Affirmative Final Results of Countervailing Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce determines that Ozdemir Boru Profil San. Ve Tic. Ltd. Sti. (Ozdemir), an exporter/producer of heavy walled rectangular welded carbon steel pipes and tubes (HWR pipes and tubes) from the Republic of Turkey (Turkey), received countervailable subsidies during the period of review (POR) December 28, 2015, through April 25, 2016, and September 12, 2016, through December 31, 2016.

DATES: Applicable November 21, 2018.

FOR FURTHER INFORMATION CONTACT: Brian Smith or Janae Martin, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–0238, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 14, 2018, Commerce published the *Preliminary Results* of the administrative review.[1] Commerce gave interested parties an opportunity to comment on the *Preliminary Results*.[2] No interested parties submitted comments. Commerce has conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are shipments of certain heavy walled rectangular welded steel pipes and tubes of rectangular (including square) cross section, having a nominal wall thickness of not less than 4 mm. The merchandise includes, but is not limited to, the American Society for Testing and Materials (ASTM) A–500, grade B specifications, or comparable domestic or foreign specifications.

Included products are those in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements below exceed the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.0 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

The subject merchandise is currently provided for in item 7306.61.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). Subject merchandise may also enter under HTSUS 7306.61.3000. While the HTSUS subheadings and ASTM specification are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Changes Since the Preliminary Results

As no parties submitted comments on the *Preliminary Results,* we made no changes in the final results of this review.

Final Results of Administrative Review

In accordance with section 777A(e)(1) of the Act and 19 CFR 351.221(b)(5), we determine the following countervailable subsidy rate during the period December 28, 2015, through April 25, 2016, and September 12, 2016, through December 31, 2016: [3]

Company	Subsidy rate (percent)
Ozdemir Boru Profil San. Ve Tic. Ltd. Sti	1.18

Assessment Rates

In accordance with 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirement

Pursuant to section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties, in the amount shown above, on shipments of subject merchandise by Ozdemir entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: November 15, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–25381 Filed 11–20–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Turkey: Preliminary Results of Countervailing Duty Administrative Review; 2016,* 83 FR 40228 (August 14, 2018) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Results,* 83 FR at 40228.

[3] As we have made no changes to this rate since the *Preliminary Results,* no additional disclosure of calculations under 19 CFR 351.224(b) is necessary for these final results.

DEPARTMENT OF COMMERCE

International Trade Administration

Request for Comments and Notice of Roundtable on Energy, Information and Communication Technology, and Infrastructure in the Indo-Pacific Region

AGENCY: Global Markets, International Trade Administration, U.S. Department of Commerce.

ACTION: Request for public comments and notice of a roundtable discussion on energy, information and communication technology (ICT), and infrastructure in the Indo-Pacific region.

SUMMARY: As part of the commitment to a free and open Indo-Pacific, the Global Markets unit of the International Trade Administration of the Department of Commerce (GM) seeks individual comments from industry on government programs to inform the catalyzation of U.S. private sector participation in commercial opportunities in the Indo-Pacific region in energy, ICT and infrastructure. Through this notice, GM announces a request for written public comments and announces a roundtable to facilitate a discussion with industry representatives and U.S. government staff. This notice serves as an initial step in improving GM's understanding of private sector interests and programmatic and policy needs in energy, ICT, and infrastructure sectors in the Indo-Pacific region. This notice further sets forth topics for discussion and comment.

DATES:

Event: The roundtable will be held on December 12, 2018, from 9:00 a.m. to 12:00 p.m., Eastern Standard Time.

Written Comments: To be ensured of consideration, written public comments must be received on or before January 4, 2019. Comments should not include any business confidential information.

Event Registration: GM will evaluate registrations based on the submitted information (see below) and inform applicants of selection decisions, which will be made on a rolling basis until 15 participants have been selected for each breakout session.

ADDRESSES:

Event: The roundtable will be held at the Department of Commerce, Room 1414, 1401 Constitution Ave. NW, Washington, DC 20230.

Comments: Written comments should be sent by electronic mail addressed to *IndoPacificOutreach@trade.gov*. Comments may also be submitted by mail addressed to: Deputy Assistant Secretary for Asia, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Room 2846, Washington, DC. Although comments may be submitted by mail, the GM prefers to receive comments via the internet.

For alternatives to online or mail submissions, please contact Stephanie Smedile, Indo-Pacific Commercial Coordinator, GM, at (202) 482–0333.

FOR FURTHER INFORMATION CONTACT: *IndoPacificOutreach@trade.gov* or Stephanie Smedile, Indo-Pacific Commercial Coordinator, GM, at (202) 482–0333

SUPPLEMENTARY INFORMATION: On July 30, 2018 the Trump Administration announced new economic initiatives in the Indo-Pacific region to advance a free and open Indo-Pacific region (*See, https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-administration-advancing-free-open-indo-pacific/*). This request for comment and event notification seeks public comment on priorities and strategies to enhance commercial engagement in each of the three initiatives announced. The initiatives and topics for public comment are as follows:

(1) Digital Connectivity and Cybersecurity Partnership (DCCP)—a new global initiative to promote access to an open, interoperable, reliable, and secure internet, with an initial focus on the Indo-Pacific region. Through this program, the United States will support communications infrastructure development through public-private partnerships, promote regulatory and policy reforms, promote exports of U.S. information and communications technology (ICT) goods and services, and build the cybersecurity capacity of our partners to address shared threats.

(2) Infrastructure Transaction and Assistance Network (ITAN)—The ITAN will prioritize support for strategically important infrastructure and catalyze opportunities for U.S. business; establish a new Indo-Pacific Transaction Advisory Fund to provide independent legal support for negotiations; and coordinate capacity-building programs to improve partner countries' project evaluation processes, regulatory and procurement environments, and project preparation and financing capabilities.

(3) Enhancing Development and Growth through Energy, or Asia EDGE, is a U.S. whole of government effort to grow sustainable and secure energy markets throughout the Indo-Pacific. Asia EDGE seeks to strengthen energy security, increase energy diversification and trade, and expand energy access across the Indo-Pacific.

The Department seeks input at the December 12th roundtable on the following topics:

- What are the principal U.S. and/or foreign policy and regulatory barriers to growing sales and exports to the Indo-Pacific region? How would you prioritize these barriers for USG engagement?
- What are the principal barriers (U.S. and/or foreign) to investment in infrastructure (ICT networks, energy, transportation, other) in countries in the Indo-Pacific?
- Have you worked with USG agencies—such as State, Commerce, USTDA, EXIM, OPIC, USAID—in doing business in the Indo-Pacific? What is your assessment of the strengths and weaknesses of the U.S. government tools to promote U.S. businesses in this sector?
- What proactive solutions or actions could the U.S. government pursue that would have an impact on catalyzing U.S. private sector participation in commercial opportunities in the Indo-Pacific region?

Event: The December 12 roundtable hosted by the Deputy Assistant Secretary for Asia will provide an overview of the President's vision for the Indo-Pacific region and will include three break-out sessions—one for each initiative—during which participants will provide insights and feedback related to the energy, ICT, and infrastructure sectors in the Indo-Pacific region. Due to limited space, the event is closed to press and observers. Industry participation is limited to 15 qualifying industry representatives per break-out session (energy, ICT, and infrastructure).

Selection

To attend, participants should submit the below information to *IndoPacificOutreach@trade.gov* by December 5, 2018. GM will evaluate registrations based on the submitted information on a rolling basis until 15 participants have been selected for each break-out session and inform applicants of selection decisions.

Applicants are encouraged to send representatives at a sufficiently senior level to be knowledgeable about their organization's capabilities, interests and challenges in the Indo-Pacific region. Please see the following hyperlink for a definition of the Indo-Pacific region: *http://www.pacom.mil/About-USINDOPACOM/USPACOM-Area-of-Responsibility/*.

Registrations should include the following information in their registration email:

- Name of attendee and short bio.
- Organization and brief organization description.
- The initiative discussion in which the registrant prefers to participate (DCCP, ITAN, or Asia EDGE). Registrants cannot register for all three as the break-outs happen concurrently. Registrants may indicate a second choice if the preferred choice is filled.
- A statement self-certifying how the organization meets each of the following criteria:

1. Is not majority owned or controlled by a foreign government entity (or foreign government entities).

2. Its existing products or services are either produced in the United States, or, if not, marketed under the name of a U.S. firm and have demonstrable U.S. content as a percentage of the value of the finished product or service AND/OR it is a major investor in projects in the Indo-Pacific in which companies with such products may compete.

3. It has already exported from the United States to or invested in the Indo-Pacific region.

4. In the case of a trade association, academic or research institution, the applicant will only be representing companies during the Roundtable that satisfy each of the criteria above.

Selection will be based on the following criteria:

- Suitability of the company's (or in the case of another organization, represented companies' or constituents') existing products or services to energy, ICT, and infrastructure commercial opportunities in the Indo-Pacific.
- Suitability of the company's (or in the case of another organization, represented companies' or constituents') experience pursuing commercial opportunities in the Indo-Pacific.

• Suitability of the representative's position and biography to be able to engage in the conversation.

Anthony Diaz,

Program Analyst, SelectUSA, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2018–25417 Filed 11–20–18; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Submission of Conservation Efforts to Make Listings Unnecessary Under the Endangered Species Act.

OMB Control Number: 0648–0466.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 1.

Average Hours per Response: 2,500 hours to complete each agreement or plan that has the intention of making listing unnecessary; 320 hours to conduct monitoring for successful agreements; and 80 hours to prepare a report for successful agreements.

Burden Hours: 2,900.

Needs and Uses: This request is for extension of a currently approved information collection.

On March 28, 2003, the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (Services) announced a final policy on the criteria the Services will use to evaluate conservation efforts by states and other non-Federal entities (68 FR 15100). The Services take these efforts into account when making decisions on whether to list a species as threatened or endangered under the Endangered Species Act. The efforts usually involve the development of a conservation plan or agreement, procedures for monitoring the effectiveness of the plan or agreement, and an annual report.

Affected Public: Business or other for-profit organizations; State, local or tribal governments.

Frequency: Annually and on occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 16, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–25368 Filed 11–20–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Patents for Humanity Program''

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office, Commerce.

Title: Patents for Humanity Program.

OMB Control Number: 0651–0066.

Form Number(s):

- PTO/PFH/001
- PTO/PFH/002
- PTO/SB/431

Type of Request: Regular.

Number of Respondents: 55 responses per year.

Average Hours per Response: The USPTO estimates that it will take the public approximately four hours to complete the humanitarian program application. Those selected as winners (about 5 to 10 per year) may additionally require one hour to complete a petition to extend their acceleration certificate redemption beyond 12 months, if needed. These estimated times include gathering the necessary information, preparing the application and any supplemental materials, and submitting the completed request to USPTO.

Burden Hours: 205 hours per year.

Cost Burden: $0 per year.

Needs and Uses: The USPTO has developed two application forms that applicants can use to apply for participation in the Patents for Humanity Program. One application covers the humanitarian uses of technologies or products and the other application covers humanitarian research. In addition, there is a form that allows applicants to provide their contact information which the USPTO uses to notify applicants that they have been selected for an award. These applications may be up to five pages long and can be supplemented with additional supporting materials. The applications must be submitted electronically through the competition website.

Applicants who are ultimately awarded a Humanitarian Award Certificate may wish to extend the redemption period of that certificate. In the event that an applicant wishes to extend that time period, they must complete a Petition to Extend the Redemption Period of the Humanitarian Awards Certificate. The petition is a one-page document which allows the applicant to request a 12-month extension of their certificate's redemption period based on criteria outlined on the form (*e.g.,* lack of a suitable matter, a pending matter is not yet ripe for certificate redemption, etc.).

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov*.

Once submitted, the request will be publically available in electronic format through *www.reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

• *Email: InformationCollection@uspto.gov*. Include ''0651–0066 copy request'' in the subject line of the message.

• *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before December 21, 2018 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Records Management Division Director, USPTO, Office of the Chief Administrative Officer.

[FR Doc. 2018–25410 Filed 11–20–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Patent Review and Derivation Proceedings''

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: United States Patent and Trademark Office, Commerce

Title: Patent Review and Derivation Proceedings.

Form Number(s): N/A.

Type of Request: Regular.

Number of Respondents: 11.994 responses per year.

Average Hours per Response: The USPTO estimates that it will take the public between an estimated 6 minutes (0.10 hours) to 165.30 hours to complete an individual form in this collection.

Burden Hours: 1,474,449 hours.

Cost Burden: $54,307,175 per year.

Needs and Uses: The public will use this information collection to petition the Board to seek the institution of—and to participate in—*inter partes* reviews, post-grant reviews, covered business method patent reviews, and derivation proceedings.

The Board disseminated information that it collections (unless filed under seal) through various publications and databases. This information collection includes the filings of the parties and decisions and orders by the Board in trials and derivation proceedings.

Opinions authored by the Board have varying degrees of authority attached to them. There are precedential opinions which, when published, are binding and provide the criteria and authority that the Board will use to decide all other factually similar cases (until the opinion is overruled or changed by statute). There are informative opinions, which are non-precedential and illustrate the norms of Board decision-making for the public. There are representative opinions, which are non-precedential and are publicly available opinions that are not designed as precedential or informative. Since public policy favors a widespread publication of opinions, the Board publishes all publicly available opinions, even if the opinions are not binding precedent upon the Board.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov*.

Once submitted, the request will be publically available in electronic format through *www.reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov*. Include ''0651–0069 copy request'' in the subject line of the message.
- *Mail:* Marcie Lovett, Records and Information Governance Division Director, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before December 21, 2018 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Records Management Division Director, USPTO, Office of the Chief Administrative Officer.

[FR Doc. 2018–25409 Filed 11–20–18; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request; ''Matters Related to First Inventor to File''

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: United States Patent and Trademark Office, Commerce.

Title: Matters Related to First Inventor to File.

OMB Control Number: 0651–0071.

Form Number(s): None.

Type of Request: Regular.

Number of Respondents: 23,681 responses per year.

Average Time per Response: The USPTO expects that it will take between 2 and 10 hours to respond to the items in this collection, depending upon the instrument used. This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Burden Hours: 207,362 hours per year.

Cost Burden: $80.40 per year.

Needs and Uses: This information collection is necessary so that patent applicants and/or patentees may: (1) Provide a statement if a nonprovisional application filed on or after March 16, 2013, other than a nonprovisional international design application, claims the benefit of, or priority to, the filing date of a foreign, provisional, or nonprovisional application filed prior to March 16, 2013, and also contains, or contained at any time, a claim to a claimed invention that has an effective filing date (as defined in 37 CFR 1.109) on or after March 16, 2013; (2) identify the inventorship and ownership or obligation to assign ownership of each claimed invention on its effective filing date (as defined in 37 CFR 1.109) or on its date of invention, as applicable, in an application or patent naming one or more joint inventors, when necessary for purposes of a USPTO proceeding; and (3) show that a disclosure was by the inventor or joint inventor, or was by a party who obtained the subject matter from the inventor or a joint inventor, or that there was a prior public disclosure by the inventor or a joint inventor, or by a party who obtained the subject matter from the inventor or a joint inventor.

The USPTO will use the statement that a nonprovisional application filed on or after March 16, 2013, other than a nonprovisional international design application, that claims the benefit of, or priority to, the filing date of a foreign, provisional, or nonprovisional application filed prior to March 16, 2013, and contains, or contained at any time, a claim to a claimed invention that has an effective filing date (as defined in 37 CFR 1.109) on or after March 16, 2013, (or lack of such a statement) to readily determine whether the nonprovisional application is subject to the changes to 35 U.S.C. 102 and 103 in the AIA. The USPTO will use the identification of the inventorship and ownership or obligation to assign ownership when it is necessary to determine whether a U.S. patent or U.S. patent application publication resulting from another nonprovisional application qualifies as prior art under 35 U.S.C. 102(a)(2) or pre-AIA 35 U.S.C. 102(e). The USPTO will use information concerning whether a disclosure was by the inventor or joint inventor, or was by a party who obtained the subject matter from the inventor or a joint inventor, or that there was a prior public disclosure by the inventor or a joint inventor, or by a party who obtained the subject matter

from the inventor or a joint inventor, to determine whether the disclosure qualifies as prior art under 35 U.S.C. 102(a)(1) or (a)(2).

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Nicholas A. Fraser, email: *Nicholas_A._Fraser@omb.eop.gov*.

Once submitted, the request will be publicly available in electronic format through *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

• *Email: InformationCollection@uspto.gov*. Include ''0651–0071 copy request'' in the subject line of the message.

• *Mail:* Marcie Lovett, Director, Records and Information Goverance Division, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before December 21, 2018 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202 395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Director, Records and Information Governance Division, Office of the Chief Adiminstrative Officer, USPTO.

[FR Doc. 2018–25408 Filed 11–20–18; 8:45 am]

BILLING CODE 350–16–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Credit Union Advisory Council Meeting

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Credit Union Advisory Council (CUAC or Council) of the Bureau of Consumer Financial Protection (Bureau). The notice also describes the functions of the Council.

DATES: The meeting date is Thursday, December 6, 2018, from approximately 1 p.m. to 3:45 p.m. eastern daylight time. The meeting will take place via conference call.

Access: The subcommittee meetings will be conducted via conference call and are open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Crystal Dully, Outreach and Engagement Associate, Consumer Advisory Board and Councils Office, External Affairs, at 202–435–9588, *CFPB_CABandCouncilsEvents@cfpb.gov*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the CUAC Charter provides that pursuant to the executive and administrative powers conferred on the Bureau of Consumer Financial Protection by section 1012 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director established the Credit Union Advisory Council under agency authority.

Section 3 of the CUAC Charter states: ''The purpose of the Advisory Council is to advise the Bureau in the exercise of its functions under the federal consumer financial laws as they pertain to community banks with total assets of $10 billion or less.''

II. Agenda

The Credit Union Advisory Council will discuss artificial intelligence in consumer financial services and consumer access to financial records.

Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the CUAC members for consideration.

Individuals who wish to join the Credit Union Advisory Council must RSVP via this link *https://consumerfinancial-protection-bureau.forms.fm/bcfp-advisory-board-and-councils-december-conference-call* by noon, December 5, 2018. Members of the public must RSVP by the due date.

III. Availability

The Council's agenda will be made available to the public on Wednesday November 21, 2018, via *consumerfinance.gov*. A summary of this meeting will be available after the meeting on the Bureau's website *consumerfinance.gov*.

Dated: November 16, 2018.

Kirsten Sutton,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25419 Filed 11–20–18; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Community Bank Advisory Council Meeting

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Community Bank Advisory Council (CBAC or Council) of the Bureau of Consumer Financial Protection (Bureau). The notice also describes the functions of the Council.

DATES: The meeting date is Thursday, December 6, 2018, from approximately 1 p.m. to 3:45 p.m. eastern daylight time. The meeting will take place via conference call.

Access: The subcommittee meetings will be conducted via conference call and are open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Crystal Dully, Outreach and Engagement Associate, Consumer Advisory Board and Councils Office, External Affairs, at 202–435–9588, *CFPB_CABandCouncilsEvents@cfpb.gov*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the CBAC Charter provides that pursuant to the executive and administrative powers conferred on the Bureau of Consumer Financial Protection by section 1012 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director established the Community

Bank Advisory Council under agency authority.

Section 3 of the CBAC Charter states: ''The purpose of the Advisory Council is to advise the Bureau in the exercise of its functions under the federal consumer financial laws as they pertain to community banks with total assets of $10 billion or less.''

II. Agenda

The Community Bank Advisory Council will discuss artificial intelligence in consumer financial services and consumer access to financial records.

Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the CBAC members for consideration.

Individuals who wish to join the Community Bank Advisory Council must RSVP via this link *https://consumer-financial-protection-bureau.forms.fm/bcfp-advisory-board-and-councils-december-conference-call* by noon, December 5, 2018. Members of the public must RSVP by the due date.

III. Availability

The Council's agenda will be made available to the public on Wednesday November 21, 2018, via *consumerfinance.gov*. A summary of this meeting will be available after the meeting on the Bureau's website *consumerfinance.gov*.

Dated: November 16, 2018.

Kirsten Sutton,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25421 Filed 11–20–18; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Consumer Advisory Board Subcommittee Meetings

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Consumer Advisory Board (CAB or Board) of the Bureau of Consumer Financial Protection (Bureau). The notice also describes the functions of the Board.

DATES: The meeting date is Thursday, December 6, 2018, from approximately 1 p.m. to 3:45 p.m. eastern daylight time. The meeting will take place via conference call.

Access: The subcommittee meetings will be conducted via conference call and are open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Crystal Dully, Outreach and Engagement Associate, Advisory Board and Councils Office, External Affairs, at 202–435–9588, *CFPB_CABandCouncilsEvents@cfpb.gov*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Charter of the Consumer Advisory Board states that:

> The purpose of the Board is outlined in section 1014(a) of the Dodd-Frank Act, which states that the Board shall ''advise and consult with the Bureau in the exercise of its functions under the Federal consumer financial laws'' and ''provide information on emerging practices in the consumer financial products or services industry, including regional trends, concerns, and other relevant information.''

To carry out the Board's purpose, the scope of its activities shall include providing information, analysis, and recommendations to the Bureau. The Board will generally serve as a vehicle for market intelligence and expertise for the Bureau. Its objectives will include identifying and assessing the impact on consumers and other market participants of new, emerging, and changing products, practices, or services.

II. Agenda

The Consumer Advisory Board will discuss artificial intelligence in consumer financial services and consumer access to financial records.

Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the CAB members for consideration. Individuals who wish to join the Consumer Advisory Board must RSVP via this link *https://consumer-financial-protection-bureau.forms.fm/bcfp-advisory-board-and-councils-december-conference-call* by noon, December 5, 2018. Members of the public must RSVP by the due date.

III. Availability

The Board's agenda will be made available to the public on Wednesday November 21, 2018, via *consumerfinance.gov*. A summary of this meeting will be available after the meeting on the Bureau's website *consumerfinance.gov*.

Dated: November 16, 2018.

Kirsten Sutton,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2018–25420 Filed 11–20–18; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Service Criminal History Check Recordkeeping Requirement

AGENCY: Corporation for National and Community Service (CNCS).

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, CNCS is proposing to renew an information collection related to the National Service Criminal History Check.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 22, 2019.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, Attention Aaron Olszewski, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except federal holidays.

(3) Electronically through *www.regulations.gov*.

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

Comments submitted in response to this notice may be made available to the public through *regulations.gov*. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Aaron Olszewski, 202–606–6670, or by email at *aolszewski@cns.gov*.

SUPPLEMENTARY INFORMATION:

Title of Collection: National Service Criminal History Check Recordkeeping.

OMB Control Number: 3045–0145.

Type of Review: Renewal.

Respondents/Affected Public: Non Profit Organizations and State, Local or Tribal Governments.

Total Estimated Number of Annual Responses: 112,357.

Total Estimated Number of Annual Burden Hours: 28,089.

Abstract: Section 189D of the National and Community Service Act of 1990, as amended requires CNCS grantees and subgrantees to conduct a National Service Criminal History Check on individuals in covered positions. Documenting compliance with the requirement is critical to that responsibility. *See* 45 CFR 2540.205–.206. CNCS also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on May 31, 2019.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov*.

Dated: November 16, 2018.

Aaron Olszewski,

Associate General Counsel.

[FR Doc. 2018–25414 Filed 11–20–18; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0091]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD (P&R)), Federal Voting Assistance Program (FVAP), DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 22, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24 Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Federal Voting Assistance Program, ATTN: Sarah Gooch, 4800 Mark Center Drive, Mailbox 10, Alexandria, VA 22350–5000 or call 703–588–1584.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Federal Write-In Absentee Ballot (FWAB); Standard Form 186; OMB Control Number 0704–0502.

Needs and Uses: The Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. 203, requires the Presidential designee (Secretary of Defense) to prescribe official forms, containing an absentee voter registration application, an absentee ballot request application and a backup ballot for use by the States to permit absent uniformed services voters and overseas voters to participate in general, special, primary and runoff elections for Federal office.

Affected Public: Individuals or Households.

Annual Burden Hours: 300,000.

Number of Respondents: 1,200,000.

Responses per Respondent: 1.

Annual Responses: 1,200,000.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

The authority for the States to collect personal information comes from UOCAVA. The burden for collecting this information resides in the States. The Federal government neither collects nor retains any personal information associated with these forms. The collected information will be used by election officials to process uniformed service members, spouses and overseas citizens who submit their information to register to vote, receive an absentee ballot or cast a write-in ballot. The collected information will be retained by election officials to provide election materials, including absentee ballots, to the uniformed services, their eligible family members and overseas voters during the form's eligibility period provided by State law. No information from the Federal Write-In Absentee Ballot (FWAB) is collected or retained by the Federal government. The applicant is required to update and resubmit the information annually, whenever they change their mailing address or as otherwise required by State law. If the information is not submitted annually or whenever they change their mailing address, the applicant may not receive ballots for elections for Federal office in that calendar year.

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–25393 Filed 11–20–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Visitors, National Defense University; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Chairman Joint Chiefs of Staff, Department of Defense.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Board of Visitors, National Defense University will take place.

DATES: Thursday, December 6, 2018 from 12:30 p.m. to 5:15 p.m. and Friday, December 7, 2018 from 10:30 a.m. to 12:15 p.m.

ADDRESSES: Marshall Hall, Building 62, Room 155A/B (Thursday), Lincoln Hall, Building 64, Room 1107 (Friday), the National Defense University, 300 5th Avenue SW, Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: Dr. Brian R. Shaw, (202) 685–4685 (Voice), (202) 685–3920 (Facsimile), *brian.r.shaw8.civ@mail.mil; brian.r.shaw.civ@ndu.edu; joycelyn.a.stevens.civ@mail.mil; stevensj7@ndu.edu* (Email). Mailing address is National Defense University, Fort McNair, Washington, DC 20319–5066. Website: *http://www.ndu.edu/About/Board-of-Visitors/*. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150. Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public.

Purpose of the Meeting: The purpose of the meeting will include discussion on accreditation compliance, organizational management, strategic planning, resource management, and other matters of interest to the National Defense University.

Agenda: Thursday, December 6, 2018 from 12:30 p.m. to 5:15 p.m.: Welcome and Administrative Notes; State of the University Address; Globally Integrated Operations; NDU Strategic Plan; State of the NDU Budget; Information Technology Update; Faculty and Staff Command Climate Survey Results and Analysis. Friday, December 7, 2018 from 10:30 a.m. to 12:15 p.m.: Condition of NDU Facilities; Public Comment, Board of Visitor Member Feedback; Wrap-up and Closing Remarks.

Meeting Accessibility: Limited space made available for observers will be allocated on a first come, first served basis. Meeting location is handicap accessible. The Main Gate/Visitor's Gate on 2nd Street SW is open 24/7. All non-DoD/non-federally affiliated visitors MUST use this gate to access Fort McNair.

ID Requirements: A federal or state government-issued photo ID with biographic information such as name, date of birth, gender, and address is required. Security badges are not acceptable. All credentials are subject to screening and vetting by Installation Access Control personnel.

Vehicle Search: Non-DoD/non-federally affiliated visitors' vehicles are subject to search.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, written statements to the committee may be submitted to the committee at any time or in response to a stated planned meeting agenda by FAX or email to Ms. Joycelyn Stevens at (202) 685–0079, Fax (202) 685–3920 or *StevensJ7@ndu.edu*.

Dated: November 16, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–25432 Filed 11–20–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0123]

Agency Information Collection Activities; Comment Request; Performance Partnership Pilots Application

AGENCY: Office of Career, Technical, and Adult Education (OCTAE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before January 22, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–

2018–ICCD–0123. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9088, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Braden Goetz, 202–245–7405.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Performance Partnership Pilots Application.

OMB Control Number: 1830–0575.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 25.

Total Estimated Number of Annual Burden Hours: 2,000.

Abstract: This information collection request solicits applications for the Performance Partnership Pilots for Disconnected Youth, which provides States, localities, or tribal governments receiving funds under multiple Federal programs additional flexibility in using these funds to achieve significant improvement in outcomes for disconnected youth.

Dated: November 16, 2018.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–25404 Filed 11–20–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Fusion Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Fusion Energy Sciences Advisory Committee. The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: December 6, 2018—8:30 a.m. to 5:00 p.m.; December 7, 2018—8:30 a.m. to 12:00 noon.

ADDRESSES: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel J. Barish, Acting Designated Federal Officer, Office of Fusion Energy Sciences (FES); U.S. Department of Energy; Office of Science; 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903–2917.

SUPPLEMENTARY INFORMATION: *Purpose of Meeting:* To provide advice on a continuing basis to the Director, Office of Science of the Department of Energy, on the many complex scientific and technical issues that arise in the development and implementation of the fusion energy sciences program.

Tentative Agenda Items

- Under Secretary for Science Perspective
- FES Perspective
- Approval of the FESAC Committee of Visitors Report
- New Long-Range Strategic Planning Activity
- Fusion Energy Sciences Roundtable on Quantum Information Science
- Public Comment
- Adjourn

Note: Remote attendance of the FESAC meeting will be possible via Zoom. Instructions will be posted on the FESAC website (*http://science.energy.gov/fes/fesac/meetings/*) prior to the meeting and can also be obtained by contacting Dr. Barish by email *sam.barish@science.doe.gov* or by phone at (301) 903–2917.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make an oral statement regarding any of the items on the agenda, you should contact Dr. Barish at (301) 903–1233 (fax) or *sam.barish@science.doe.gov* (email). Reasonable provision will be made to include the scheduled oral statements during the Public Comment time on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available for public review and copying within 30 days on the Fusion Energy Sciences Advisory Committee website—*http://science.energy.gov/fes/fesac/*.

Signed in Washington, DC, on November 16, 2018.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2018–25382 Filed 11–20–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–2400–001.

Applicants: New York Independent System Operator, Inc.

Description: Compliance filing: NYISO amended compliance filing—uplift reporting Order No 844 to be effective 3/15/2019.

Filed Date: 11/15/18.

Accession Number: 20181115–5149.

Comments Due: 5 p.m. ET 12/6/18.

Docket Numbers: ER18–2449–001.

Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.

Description: Tariff Amendment: 2018–11–15_SA 3167 Enbridge-SWL&P FRA Substitute (Nemadji) to be effective 9/19/2018.

Filed Date: 11/15/18.

Accession Number: 20181115–5132.

Comments Due: 5 p.m. ET 12/6/18.

Docket Numbers: ER19–310–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2018–11–15_SA 3200_Sholes Wind-MidAmerican Substitute Original FCA (C027) to be effective 10/25/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5164.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–341–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–14_SA 1756 METC-Consumers Energy 12th Rev GIA (G479B) to be effective 11/1/2018.
Filed Date: 11/14/18.
Accession Number: 20181114–5127.
Comments Due: 5 p.m. ET 12/5/18.
Docket Numbers: ER19–342–000.
Applicants: Lancaster County Solid Waste Management Authority.
Description: Baseline eTariff Filing: Reactive Power Tariff Application to be effective 1/1/2019.
Filed Date: 11/14/18.
Accession Number: 20181114–5133.
Comments Due: 5 p.m. ET 12/5/18.
Docket Numbers: ER19–343–000.
Applicants: ISO New England Inc., New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: ISO–NE and NEPOOL; Updates to Assumptions Used in the ICR and Related Values to be effective 1/14/2019.
Filed Date: 11/15/18.
Accession Number: 20181115–5049.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–344–000.
Applicants: Georgia Power Company.
Description: § 205(d) Rate Filing: GPCo 2018 PBOP Filing to be effective 1/1/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5060.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–345–000.
Applicants: Mississippi Power Company.
Description: § 205(d) Rate Filing: PBOP 2018 Filing to be effective 1/1/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5066.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–346–000.
Applicants: Southern Electric Generating Company.
Description: § 205(d) Rate Filing: SEGCo 2018 PBOP Filing to be effective 1/1/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5067.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–347–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–15_SA 3205 Clinton Wind-Duke Energy GIA (J446) to be effective 10/31/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5100.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–348–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to 5 Service Agreements re: Transfer of parent company to Glidepath to be effective 7/13/2004.
Filed Date: 11/15/18.
Accession Number: 20181115–5146.
Comments Due: 5 p.m. ET 12/6/18.
Docket Numbers: ER19–349–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–15_Termination of SA 2914 NSP-Ashtabula Wind IV FCA (C019) to be effective 12/1/2018.
Filed Date: 11/15/18.
Accession Number: 20181115–5150.
Comments Due: 5 p.m. ET 12/6/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 15, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–25371 Filed 11–20–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2015–0641; FRL–9986–92–OW]

Proposed Information Collection Request; Comment Request; Information Collection Request for Reporting Requirements for BEACH Act Grants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Information Collection Request for Reporting Requirements for BEACH Act Grants'' (EPA ICR No. 2048.06, OMB Control No. 2040–0244) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through July 31, 2019. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments must be submitted on or before January 22, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2015–0641 to the EPA (1) online using *www.regulations.gov* (our preferred method), or (2) by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

The EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Tracy Bone, OW, 4305T, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–5257; email address: *bone.tracy@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov*

or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about the EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The Beaches Environmental Assessment and Coastal Health (BEACH) Act amends the Clean Water Act (CWA) in part and authorizes the U.S. Environmental Protection Agency (EPA) to award BEACH Act Program Development and Implementation Grants to coastal and Great Lakes states, tribes, and territories (collectively referred to as jurisdictions) for their beach monitoring and notification programs. The grants assist those jurisdictions to develop and implement a consistent approach to monitor recreational water quality; assess, manage, and communicate health risks from waterborne microbial contamination; notify the public of pollution occurrences, and post beach advisories and closures to prevent public exposure to microbial pathogens. To qualify for a BEACH Act Grant, a jurisdiction must submit information to the EPA documenting that its beach monitoring and notification program is consistent with performance criteria outlined in the *National Beach Guidance and Required Performance Criteria for Grants, 2014 Edition*.

Form numbers: None.

Respondents/affected entities: Entities potentially affected by this action are environmental and public health agencies in coastal and Great Lakes states, territories, and tribes.

Respondent's obligation to respond: Required to obtain the grants as directed by the BEACH Act amendment to the CWA.

Estimated number of respondents: 39.

Frequency of response: Annual; however, the agency encourages more frequent reporting to provide more up-to-date information to the public.

Total estimated burden: 88,569 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $14,865,812 (per year), includes $11,063,780 (per year) operation & maintenance costs. There are no capital costs.

Changes in estimates: There is a decrease of 2,707 hours in the total respondent burden compared with the ICR approved by OMB in July 2015 due to the respondents no longer needing to prepare and submit schedules for the adoption of new or revised WQS and identification and use of a beach notification threshold (BNT). The EPA no longer requests respondents submit these schedules because they are using BNTs or alternate BNTs and have either adopted new or revised WQS or are in the process of doing so. This decrease in hours is partially offset by one additional tribe having qualified for a BEACH grant. The total respondent cost decreased by $587,496. The decrease in cost is partially offset by slight increases in the salary rates. The O&M decreased by $289,366 due to a reduction in the total number of beaches (affecting O&M). The number of beaches reported by the jurisdictions varies from year to year for many reasons. Reasons for removing beaches include the destruction of beaches by natural disasters, change in beach ownership, and existing beaches being combined within a jurisdiction's monitoring and notification program.

Dated: November 13, 2018.

Deborah G. Nagle,

Acting Director, Office of Science and Technology.

[FR Doc. 2018–25423 Filed 11–20–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2018–0614; FRL–9986–79–OW]

Request for Public Review and Comment: Draft Human Health Toxicity Assessments for Hexafluoropropylene Oxide Dimer Acid and Its Ammonium Salt (GenX Chemicals) and for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period associated with the release of two draft toxicity assessments for public comment:

- Draft Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt (GenX Chemicals).
- Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate.

The EPA developed the draft assessments to provide the health effects information available for GenX chemicals and PFBS and describe how that information was used to derive draft toxicity values. These draft toxicity assessments underwent independent, external expert peer review in June-July 2018. Following closure of this 60-day public comment period, the EPA will consider the comments, revise the draft documents, and consider the need for additional peer review, as appropriate, and then publish final toxicity assessments. The toxicity assessments for GenX chemicals and PFBS are scientific and technical reports that include toxicity values associated with potential noncancer health effects following oral exposure (in this case, oral reference doses [RfDs]). These assessments evaluate human health hazards. The toxicity assessments and the values contained within are not risk assessments as they do not include exposure assessments or provide a risk characterization. Further, the toxicity assessments do not address the legal, political, social, economic, or technical considerations involved in risk management. When issued, the toxicity assessments can be used by the EPA, states, tribes, and local communities, along with specific exposure and other relevant information, to determine, under the appropriate regulations and statutes, if and when it is necessary to

take action to address potential risk associated with human exposures to these per- and polyfluoroalkyl substances (PFAS) chemicals.

DATES: Comments must be received on or before January 22, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2018–0614, to the public docket at: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT:

For information on the docket, contact the docket manager: Assem Akram, Docket Manager, EPA Docket Center, telephone: (202) 566–0226; or email: *Akram.Assem@epa.gov*.

For technical information on GenX chemicals: Dr. Jamie Strong, Health and Ecological Criteria Division, Office of Water (Mail Code 4304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone: (202) 566–0056; or email: *strong.jamie@epa.gov*.

For technical information on PFBS: Dr. Samantha Jones, National Center for Environmental Assessment, Office of Research and Development (Mail Code 8602R), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone: 202–564–6794; or email: *jones.samantha@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

Supporting documents are available in the public docket for this ICR (under Docket ID number EPA–HQ–OW–2018–0614. The docket can be viewed online at *http://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about the EPA's public docket, visit *http://www.epa.gov/dockets*.

A. Does this action apply to me?

This request for public comment will not impose any requirements on anyone. Instead, this action notifies interested parties of the availability of draft toxicity assessments for GenX Chemicals and PFBS for public comment. It should be noted that when final these toxicity assessments may be used by the EPA, states, tribes, and local communities, along with specific exposure and other relevant information, to determine, under the appropriate regulations and statutes, if and when it is necessary to take action to address potential risk associated with human exposures to these PFAS chemicals.

B. What should I consider as I prepare my comments for the EPA?

1. Submit your comments, identified by Docket ID No. EPA–HQ–OW–2018–0614, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to the EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in the *Code of Federal Regulations* (CFR) at 40 CFR part 2. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. What are GenX chemicals and PFBS?

GenX chemicals and PFBS are man-made, fluorinated organic chemicals that are part of a larger group of manmade chemicals referred to as per- and polyfluoroalkyl substances (PFAS). PFAS are used in many applications because of their unique physical properties such as resistance to high and low temperatures, resistance to degradation, and nonstick characteristics. GenX is a trade name for a processing aid technology used to make high-performance fluoropolymers without the use of perfluorooctanoic acid (PFOA). Hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt are the major chemicals associated with the GenX processing aid technology and the focus of the draft assessment. PFBS is a four-carbon PFAS that was developed as a replacement for longer-chain PFAS, which have demonstrated environmental persistence, long half-lives and bioaccumulation in humans. PFBS has been integrated into various consumer products and applications.

III. What are EPA's draft toxicity assessments?

The EPA's draft toxicity assessments for GenX Chemicals and PFBS provide information on hazard identification and dose-response, including draft subchronic and chronic oral reference doses (RfDs) for each chemical. Overall, the available oral toxicity studies demonstrate that the liver is particularly sensitive to GenX chemicals, and the thyroid and kidney are sensitive to PFBS. The draft toxicity assessments underwent independent, external peer review in June and July 2018 and were revised accordingly.

In the risk assessment/risk management paradigm, a toxicity assessment is on the risk assessment side of the paradigm. The draft toxicity assessments for GenX chemicals and PFBS address the first two steps (Step 1. Hazard Identification and Step 2. Dose-Response) of the four-step risk assessment process described by the National Academy of Science in 1983 as ''the characterization of the potential adverse health effects of human exposures to environmental hazards.''

Characterizing risk involves integrating information on hazard, dose-response, and exposure. For further details about risk assessments see: *https://www.epa.gov/risk/conducting-human-health-risk-assessment.*

When issued, the toxicity values for GenX chemicals and PFBS can be combined with specific exposure information (Step 3. Exposure Assessment) by government and private entities to help characterize (Step 4. Risk Characterization) potential public health risks associated with exposure to these chemicals. Thus, once the GenX chemicals and PFBS assessments are issued, the EPA will work with our state, tribal, and local partners to provide technical assistance, including information about appropriate regulations and statutes, as they begin considering the final values in relevant exposure scenarios. It is the risk management part of the risk assessment/risk management paradigm where the supporting science, as well as statutory and legal considerations, risk management options, public health considerations, cost/benefit considerations, economic factors, social factors, and other considerations are weighed.

The EPA recognizes that humans have the potential to be exposed to complex mixtures of PFAS and other chemicals and pathogens through drinking water and other exposure sources. The EPA's draft assessments for GenX chemicals and PFBS focus solely on the potential human health effects associated with oral exposure to each chemical; they do not consider potential cumulative (mixture) effects of GenX chemicals and PFBS or their possible interactions with other PFAS and/or other chemicals. This would involve a more complex assessment that would need to consider and evaluate mechanisms of action and endpoints of concern for each of the chemicals in the mixture.

IV. Why is the EPA releasing draft toxicity assessments for these chemicals?

The EPA is issuing the draft toxicity assessments for PFBS and GenX chemicals for public comment to give interested stakeholders and the public an opportunity to provide input to the Agency. The public will have 60 days after publication in the **Federal Register** to provide input. At the end of the comment period, the EPA will evaluate the input, make appropriate revisions, and finalize the toxicity assessments. Once the toxicity assessments are issued, the EPA will work with our state, tribal, and local partners to provide technical assistance, as they begin using the final values in relevant exposure scenarios to generate risk assessments to support risk management decisions.

V. Solicitation of Public Comment

During the 60-day comment period, the EPA is soliciting public comments regarding the science and technical approaches used in the derivation of the draft toxicity assessments for GenX chemicals and PFBS.

In the PFBS assessment, due to the lack of epidemiological studies demonstrating adverse effects in humans, the EPA derived candidate subchronic RfDs (see Section 6.1.1 of the toxicity assessment) and candidate chronic RfDs (see Section 6.1.2 of the toxicity assessment) for both thyroid effects and kidney effects in rodent toxicity studies. In light of the consistent observation of the thyroid effects across life stages and the greater dose-response sensitivity, relative to the kidney effects, the EPA is proposing to base the overall subchronic and chronic RfDs on the thyroid effects and is requesting public review and comment on this proposal in addition to the approaches and conclusions in the PFBS assessment. Additionally, as described in Section 6.1 of the PFBS toxicity assessment, decreased serum total T4 (thyroxine) in newborn mice was used as the basis for the thyroid-related candidate RfDs. Peer reviewers provided comments on thyroid effects and this choice of endpoint. See pages 15–25 and 31–32 in the *Response to Peer Review Comments on the Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375–73–5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420–49–3)* for the array of peer review comments on these topics and the EPA's responses. These supporting documents are available in the public docket for this ICR (under Docket ID number EPA–HQ–OW–2018–0614. Comments from the public are requested on the thyroid effects, this choice of endpoint, as well as the discussion on thyroid hormone economy in humans and animals (see Section 6.1 of the PFBS toxicity assessment).

These draft assessments are not final as described in the EPA's information quality guidelines, and do not represent Agency policy or views. The EPA will consider all public comments submitted in response to this notice when revising these documents.

Dated: November 14, 2018.

David P. Ross,

Assistant Administrator, Office of Water.

[FR Doc. 2018–25422 Filed 11–20–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Systemic Resolution Advisory Committee; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Systemic Resolution Advisory Committee, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on a broad range of policy issues regarding the resolution of systemically important financial companies.

DATES: Thursday, December 6, 2018, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of a range of issues and developments related to the resolution of systemically important financial companies. The agenda may be subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This meeting of the FDIC Systemic Resolution Advisory

Committee will be Webcast live via the internet *http://fdic.windrosemedia.com*. Questions or troubleshooting help can be found at the same link. For optimal viewing, a high-speed internet connection is recommended. Further, a video of the meeting will be available on-demand approximately two weeks after the event.

Dated: November 16, 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2018–25366 Filed 11–20–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A Copy of the agreement is available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 011707–016.

Agreement Name: Gulf/South America Discussion Agreement.

Parties: BBC Chartering Carriers GmbH & Co. KG; Industrial Maritime Carriers, LLC; Seaboard Marine Ltd.; and ZEAMARINE Carrier GmbH.

Filing Party: Wade Hooker.

Synopsis: The amendment removes the sections into which the parties are currently divided, adds ad hoc space charter authority, adds joint service contract authority, and adds ZEAMARINE Carrier GmbH as a party to the Agreement.

Proposed Effective Date: 12/27/2018.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/684.

Dated: November 16, 2018.

Rachel Dickon,

Secretary.

[FR Doc. 2018–25389 Filed 11–20–18; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MARITIME COMMISSION

[Docket No. 18–10]

Logfret, Inc., Complainant v. Kirsha, B.V., Leendert Johanness Bergwerff a/k/a Hans Bergwerff, Linda Sieval, Respondents; Notice of Filing of Complaint and Assignment

November 16, 2018.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Logfret, Inc., hereinafter ''Complainant'', against Kirsha, B.V., Leendert Johanness Bergwerff a/k/a Hans Bergwerff, and Linda Sieval, hereinafter ''Respondents''. Complainant states that it ''. . . provides transport, logistics and related shipping services to customers in the United States and worldwide'' and is licensed by the Commission. Complainant states that it ''. . . is an affiliate of Logfret, B.V. . . . '' Complainant states that ''. . . Respondent Kirsha, B.V. is a corporation organized and existing under the laws of the Netherlands. . . .'' Complainant states that ''Respondent Ms. Linda Sieval, a Dutch national, was a sales manager for Logfret B.V. until the termination of her employment on March 1, 2018. Complainant states that Respondent Mr. Hans Bergwerff, is ''. . . a Dutch national, who exercises signatory authority and direct control over Kirsha, B.V.''

Complainant alleges that Respondents, in the course of their management of Logret B.V., violated 46 U.S.C. 41103(a) by unlawfully routing shipments to a competitor, and improper use of Complainant's bill of lading.

Complainant seeks reparations in the amount of $2,000,000 and other relief. The full text of the complaint can be found in the Commission's Electronic Reading Room at *www.fmc.gov/18-10*.

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by November 18, 2019, and the final decision of the Commission shall be issued by June 1, 2020.

Rachel E. Dickon,

Secretary.

[FR Doc. 2018–25415 Filed 11–20–18; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 7, 2018.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *2018 Grantor Trust FBO Rachel Grimstad and 2018 Grantor Trust FBO Gus Grimstad, with Padrin Grimstad as trustee, together with the 2018 Grantor Trust FBO Max Grimstad and 2018 Grantor Trust FBO Oscar Grimstad, with Ann Grimstad as trustee, all of Decorah, Iowa;* to join the Grimstad Family Control Group approved on September 21, 2005, and acquire voting shares of Security Agency, Inc., and thereby indirectly acquire voting shares of Decorah Bank and Trust Company, both in Decorah, Iowa.

Board of Governors of the Federal Reserve System, November 16, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–25383 Filed 11–20–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to revise for three years, without extension, the Capital Assessments and Stress Testing (FR Y–14A/Q/M; OMB No. 7100–0341). The revisions are applicable with the reports as of December 31, 2018.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final Approval Under OMB Delegated Authority of the Revision, Without Extension, of the Following Information Collection:

Report title: Capital Assessments and Stress Testing.

Agency form number: FR Y–14A/Q/M.

OMB control number: 7100–0341.

Effective Date: December 31, 2018.

Frequency: Annually, semi-annually, quarterly, and monthly.

Respondents: The respondent panel consists of any top-tier bank holding company (BHC) that has $100 billion or more in total consolidated assets, as determined based on: (i) The average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's FR Y–9C; or (ii) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters. The respondent panel also consists of any U.S. intermediate holding company (IHC). Reporting is required as of the first day of the quarter immediately following the quarter in which the respondent meets this asset threshold, unless otherwise directed by the Board.

Estimated number of respondents: 36.

Estimated average hours per response: FR Y–14A: Summary, 887 hours; Macro Scenario, 31 hours; Operational Risk, 18 hours; Regulatory Capital Instruments, 21 hours; Business Plan Changes, 16 hours; and Adjusted Capital Plan Submission, 100 hours. FR Y–14Q: Retail, 15 hours; Securities, 13 hours; PPNR, 711 hours; Wholesale, 151 hours; Trading, 1,926 hours; Regulatory Capital Transitions, 23 hours; Regulatory Capital Instruments, 54 hours; Operational Risk, 50 hours; MSR Valuation, 23 hours; Supplemental, 4 hours; Retail FVO/HFS, 15 hours; Counterparty, 514 hours; and Balances, 16 hours. FR Y–14M: 1st Lien Mortgage, 516 hours; Home Equity, 516 hours; and Credit Card, 512 hours. FR Y–14 On-going Automation Revisions, 480 hours. FR Y–14 Attestation On-going Audit and Review, 2,560 hours.

Estimated annual reporting hours: FR Y–14A: Summary, 63,864 hours; Macro Scenario, 2,232 hours; Operational Risk, 648 hours; Regulatory Capital Instruments, 756 hours; Business Plan Changes, 576 hours; and Adjusted Capital Plan Submission, 500 hours. FR Y–14Q: Retail, 2,160 hours; Securities, 1,872 hours; Pre-Provision Net Revenue (PPNR), 102,385 hours; Wholesale, 21,744 hours; Trading, 92,448 hours; Regulatory Capital Transitions, 3,312 hours; Regulatory Capital Instruments, 7,776 hours; Operational risk, 7,200 hours; Mortgage Servicing Rights (MSR) Valuation, 1,380 hours; Supplemental, 576 hours; Retail Fair Value Option/Held for Sale (Retail FVO/HFS), 1,500 hours; Counterparty, 24,672 hours; and Balances, 2,304 hours. FR Y–14M: 1st Lien Mortgage, 210,528 hours; Home Equity, 173,376 hours; and Credit Card, 86,016 hours. FR Y–14 On-going Automation Revisions, 17,280 hours. FR Y–14 Attestation On-going Audit and Review, 33,280 hours.

General description of report: These collections of information are applicable to top-tier BHCs with total consolidated assets of $100 billion or more and U.S. IHCs. This family of information collections is composed of the following three reports:

- The semi-annual FR Y–14A, which collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios, and qualitative information on methodologies used to develop internal projections of capital across scenarios.[1]
- The quarterly FR Y–14Q, which collects granular data on various asset classes, including loans, securities, trading assets, and pre-provision net revenue (PPNR) for the reporting period.
- The monthly FR Y–14M, which is comprised of three retail portfolio- and loan-level schedules, and one detailed address matching schedule to supplement two of the portfolio- and loan-level schedules.

Respondent firms are currently required to submit up to 18 filings each year: 2 semi-annual FR Y–14A filings, 4 quarterly FR Y–14Q filings, and 12 monthly FR Y–14M filings.

Legal authorization and confidentiality: The FR Y–14 A/Q/M reports are mandatory. The Board has the authority to require BHCs to file the FR Y–14A/Q/M reports pursuant to section 5 of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1844), and to require the U.S. IHCs of Foreign Banking Organizations to file the FR Y–14 A/Q/M reports pursuant to section 5 of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106).

The information collected in these reports is collected as part of the Board's supervisory process, and therefore is afforded confidential treatment pursuant to exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). In addition, individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Determinations of confidentiality based on exemption 4 of FOIA would be made on a case-by-case basis.

Current actions: On August 8, 2018, the Board published a notice in the **Federal Register** (83 FR 39093) requesting public comment for 60 days on the revision, without extension, of the Capital Assessments and Stress Testing (FR Y–14A/Q/M). The Board proposed revising sub-schedule L.5 (Derivatives and SFT Profile) of the FR Y–14Q, Schedule L (Counterparty) by adding back mistakenly omitted items for total stressed net current exposure to be reported under the two supervisory stressed scenarios. With the addition of these items, the instructions would be

[1] Firms that must re-submit their capital plan generally also must provide a revised FR Y–14A in connection with their resubmission. See 12 CFR 225.8(d)(4).

changed to modify the associated ranking methodologies for the yearly stressed/CCAR submission in sub-schedule L.5 to require the top 25 counterparties to be reported as ranked by the total stressed net current exposure. The comment period for this notice expired on October 9, 2018. The Board received one comment from a banking organization. The commenter requested that the Board adopt these changes and publish the associated materials as soon as possible in order to provide adequate time to implement and test the changes. The Board strives to provide as much time as possible in advance of the effective date for firms to implement revisions. The draft forms and instructions were made available with the publication of the initial notice. The revisions, including draft forms and instructions, will be implemented as proposed as of December 31, 2018.

Board of Governors of the Federal Reserve System, November 15, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–25339 Filed 11–20–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Reporting, Recordkeeping, and Disclosure Requirements Associated with the Home Mortgage Disclosure Act (HMDA) and Loan/Application Register (LAR) required by Regulation C (FR HMDA LAR, OMB No. 7100–0247).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following information collection:

Report title: Reporting, Recordkeeping, and Disclosure Requirements Associated with the Home Mortgage Disclosure Act (HMDA) and Loan/Application Register (LAR) required by Regulation C.

Agency form number: FR HMDA LAR.

OMB control number: 7100–0247.

Frequency: Annually and quarterly.

Respondents: State member banks (SMBs), their subsidiaries, subsidiaries of bank holding companies, U.S. branches and agencies of foreign banks (other than federal branches, federal agencies, and insured state branches of foreign banks), commercial lending companies owned or controlled by foreign banks, and organizations operating under section 25 or 25A of the Federal Reserve Act.

Estimated number of respondents: Update policies, procedures, and systems (one-time), 505 respondents; Reporting—Tier 1 (annual reporter), 2 respondents; Tier 1 (quarterly reporter), 1 respondent; Tier 2, 148 respondents; Tier 2 (Crapo), 300 respondents; and Tier 3 (Crapo), 54 respondents; Recordkeeping—Tier 1 (annual reporter), 2 respondents; Tier 1 (quarterly reporter), 1 respondent; Tier 2, 448 respondents; and Tier 3, 54 respondents; and Disclosure—Tier 1 (annual reporter), 2 respondents; and Tier 1 (quarterly reporter), 1 respondent.

Estimated average hours per response: Update policies, procedures, and systems (one-time), 176 hours; Reporting—Tier 1 (annual reporter), 5,969 hours; Tier 1 (quarterly reporter), 6,903 hours; Tier 2, 1,232 hours; Tier 2 (Crapo), 986 hours; and Tier 3 (Crapo), 64 hours; Recordkeeping—Tier 1 (annual reporter), 4,130 hours; Tier 1 (quarterly reporter), 4,130 hours; Tier 2, 83 hours; and Tier 3, 27 hours; and Disclosure—Tier 1 (annual reporter), 5 hours; and Tier 1 (quarterly reporter), 5 hours.

Estimated annual burden hours: Update policies, procedures, and systems (one-time), 88,880 hours; Reporting—Tier 1 (annual reporter), 11,938 hours; Tier 1 (quarterly reporter), 27,612 hours; Tier 2, 182,336 hours; Tier 2: Crapo, 295,800 hours; and Tier 3: Crapo, 3,456 hours; Recordkeeping—Tier 1 (annual reporter), 8,260 hours; Tier 1 (quarterly reporter), 16,520 hours; Tier 2, 37,184 hours; and Tier 3, 1,458 hours; and Disclosure—Tier 1 (annual reporter), 10 hours; and Tier 1 (quarterly reporter), 20 hours.

General description of report: HMDA was enacted in 1975 and is implemented by Regulation C. Generally, HMDA requires certain depository and non-depository institutions that make certain mortgage loans to collect, report, and disclose data about originations and purchases of mortgage loans, as well as loan applications that do not result in originations (for example, applications that are denied or withdrawn). HMDA was enacted to provide regulators and the public with loan data that can be used to: (1) Help determine whether financial institutions are serving the housing needs of their communities, (2) assist public officials in distributing public-sector investments so as to attract private investment to areas where it is needed, and (3) assist in identifying possible discriminatory lending patterns and enforcing anti-discrimination statutes.[1] Supervisory agencies, state and local public officials, and members of the public use the data to aid in the enforcement of the Community Reinvestment Act, the Equal Credit Opportunity Act, and the Fair Housing Act and to aid in identifying areas for residential redevelopment and rehabilitation.

Legal authorization and confidentiality: The FR HMDA LAR is authorized pursuant to section 304(j) of HMDA (12 U.S.C. 2803(j)), which requires that the Bureau of Consumer Financial Protection (Bureau) prescribe by regulation the form of loan application register information that must be reported by covered financial institutions. Section 1003.5 of Regulation C implements this statutory provision, and requires covered financial institutions to submit reports

[1] 12 CFR 1003.1(b).

to their appropriate federal agency. Section 304(h)(2)(A) of HMDA (12 U.S.C. 2803(h)(2)(A)) designates the Board as the appropriate agency with respect to the entities described above. The FR HMDA LAR is mandatory. HMDA requires the information collected on the FR HMDA LAR to be made available to the general public in the form proscribed by the Bureau. The Bureau is authorized to redact or modify the scope of the information before it is publicly disclosed to protect the privacy of loan applicants and to protect depository institutions from liability under any federal or state privacy law (12 U.S.C. 2803(j)(2)(B)). The redacted information may be kept confidential under exemption 6 of the Freedom and Information Act, which protects from release information that, if disclosed, would ''constitute a clearly unwarranted invasion of personal privacy'' (5 U.S.C. 552(b)(6)).

Current actions: On August 28, 2018, the Board published a notice in the **Federal Register** (83 FR 43868) requesting public comment for 60 days on the extension, with revision, of the Reporting, Recordkeeping, and Disclosure Requirements Associated with the Home Mortgage Disclosure Act (HMDA) and Loan/Application Register (LAR) required by Regulation C. Consistent with the Bureau's final rules amending Regulation C, effective January 1, 2018, as well as recent statutory amendments to HMDA that were enacted on May 24, 2018,[2] the Board proposes to revise the FR HMDA LAR by expanding the data reported and by modifying the types of institutions required to report and the types of loans required to be reported. Beginning January 1, 2018, an institution that is otherwise not eligible for a partial exemption under section 104(a) of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA), as discussed further below, is required to collect and report all required data points required under HMDA if it *either* originates 25 or more [3] closed-end mortgage loans *or* 500 or more open-end lines of credit [4] secured by a dwelling in each of the two preceding years, in addition to meeting other applicable coverage criteria.[5] For these institutions, the final rules standardize the loan volume threshold used to determine coverage of both depository and non-depository institutions. An institution will only report a covered loan if it has met the loan origination threshold for that loan category (open-end or closed-end).

The final rules generally will require covered institutions to collect and report any mortgage loan secured by a dwelling, including open-end lines of credit, regardless of the loan's purpose. However, the final rules exclude unsecured home-improvement loans (which historically were required to be reported), dwelling-secured loans that are made principally for a commercial or business purpose, agricultural-purpose loans, and other specifically excluded loans.[6]

The final rules also will require collection of additional data points. For covered institutions that are otherwise not eligible for the partial exemption under section 104(a) of EGRRCPA, as discussed further below, these additional data points will be reported in 2019. These new fields include

- Additional information about the applicant or borrower, such as age and credit score
- information about the loan pricing, such as the borrower's total cost to obtain a mortgage, temporary introductory rates, and borrower-paid origination charges
- information about loan features, such as the loan term, prepayment penalties, or non-amortizing features (such as interest only or balloon payments)
- additional information about property securing the loan, such as property value and property type

In addition, the Bureau's final rules amend several existing requirements, including the requirements for collection and reporting of information regarding an applicant's or borrower's ethnicity, race and sex.[7]

Effective May 24, 2018, an institution that is eligible for the partial exemption under section 104(a) of EGRRCPA will only need to report a subset of the data points required under HMDA if it originates fewer than 500 closed-end mortgage loans in each of the two preceding calendar years.[8] Consistent with section 104(a) of EGRRCPA and the Bureau's recent statement addressing the applicability of this statutory amendment to HMDA,[9] the Board estimates that institutions eligible for the partial exemption will report approximately half the data points currently required by the Bureau's final rules on the loans described above.[10]

The Bureau will collect the HMDA/LAR data on behalf of the applicable Federal supervisory agency, and the data will be combined and aggregated for each Metropolitan Statistical Area (MSA). Certain aggregated data will continue to be publicly available, though the Bureau has yet to determine what the information collected in the new data fields will be disclosed once the final rules are fully effective. The comment period for this notice expired on October 29, 2018. The Board did not receive any comments. The revisions will be implemented as proposed.

[2] On May 24, 2018, the President signed into law the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA). In relevant part, section 104(a) of EGRRCPA amends HMDA to exempt certain insured depository institutions and insured credit unions from collecting and reporting those data fields that were required by HMDA sections 304(b)(5) and (6), as implemented by the Bureau's final rules.

[3] Small depository institutions that originated fewer than 25 closed-end mortgage loans in either 2015 or 2016 ceased HMDA data collection on January 1, 2017.

[4] Under the 2015 final rules, financial institutions would have been required to report home-equity lines of credit if they made 100 or more such loans in each of the last two years. On August 24, 2017, the Bureau amended the final rules to increase the institutional coverage and loan threshold from 100 to 500 or more loans through calendar years 2018 and 2019. *See* 82 FR 43088 (Sept. 13, 2017). This temporary increase in the threshold will provide time for the Bureau to consider whether to initiate another rulemaking to address the appropriate level for the threshold for data collected beginning January 1, 2020.

[5] Asset size and geographic location coverage tests also apply. *See* 12 CFR FR 1003.2(g).

[6] 12 CFR 1003.2(e).

[7] For the complete list of data points, *see* 12 CFR 1003.4.

[8] Section 104(a) of EGRRCPA also provides a partial exemption to the data collection and reporting requirements under HMDA for institutions that originate fewer than 500 open-end lines of credit in each of the two preceding calendar years and otherwise meet the applicable performance evaluation rating standards under CRA. However, institutions eligible for this partial exemption are already completely exempt from *all* data collection and reporting requirements under the temporary exemption provided by the Bureau's final rules until January 1, 2020.

[9] See *Bureau Statement,* which provides that for loans subject to the partial exemption, ''the requirements of [HMDA section 304(b)(5) an (6)] shall not apply . . . [therefore,] institutions are exempt from the collection, recording, and reporting requirements for some, but not all, of the data points specified in current Regulation C.''

[10] Section 104(a) of EGRRCPA does not define the terms ''closed-end loan'' or ''open-end line of credit.'' However, for purposes of estimating burden, the Board is making the assumption that these terms will be used consistent with how they are currently defined in Regulation C. *See* 12 CFR 1002.2(d) and (o), which defines the term ''closed-end loan'' and ''open-end line of credit,'' respectively. Further, for purposes of estimating burden, the Board is making the assumption that the loan volume thresholds for closed-end loans will be determined consistent with how such loan thresholds are currently used under Regulation C to determine if a transaction must be reported. See 12 CFR 1003.3(c)(11) and (12), which provides how to determine the loan threshold volume for closed-end loan reporters and open-end line of credit reporters, respectively.

Board of Governors of the Federal Reserve System, November 15, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–25338 Filed 11–20–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The President's Committee for People with Intellectual Disabilities (PCPID) will host a webinar/conference call for its members to discuss the potential topics of the Committee's 2019 Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a discussion format.

DATES: *Webinar/Conference Call:* Wednesday, December 5, 2018 from 9:00 a.m. to 10:00 a.m. (EST).

FOR FURTHER INFORMATION CONTACT: Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW, Switzer Building, Room 1114, Washington, DC 20201. Telephone: 202–795–7334. Fax: 202–795–7334. Email: *Allison.Cruz@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: The purpose of this virtual meeting is to discuss the Committee's preparation of the PCPID 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Webinar/Conference Call: The webinar/conference call is scheduled for Wednesday, December 5, 2018, 9:00 a.m. to 10:00 a.m. (EST) and may end early if discussions are finished.

Instructions to Participate in the Webinar/Conference Call on Wednesday, December 5, 2018: Please dial: (888) 949–2790; Pass Code: 1989852

Background Information on the Committee: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expanding employment opportunities; (B) connecting people to services; (C) supporting families and caregivers; (D) strengthening the networks; and (E) protecting rights and preventing abuse.

Dated: November 15, 2018.

Julie Hocker,

Commissioner, Administration on Disabilities (AoD).

[FR Doc. 2018–25375 Filed 11–20–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3522]

Use of the Names of Dairy Foods in the Labeling of Plant-Based Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** of September 28, 2018. In the notice, FDA invited interested parties to provide information on specific topics related to the labeling of plant-based products with names that include the names of dairy foods such as ''milk,'' ''cultured milk,'' ''yogurt,'' and ''cheese.'' We are extending the comment period to give interested parties more time to comment.

DATES: FDA is extending the comment period on the notice published in the **Federal Register** of September 28, 2018 (83 FR 49103). Submit either electronic or written comments by January 28, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 28, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 28, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3522 for ''Use of the Names of Dairy Foods in the Labeling of Plant-Based Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mabel Lee, Center Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 28, 2018 (83 FR 49103), FDA published a notice with a 60-day comment period inviting interested parties to provide information on specific topics related to the labeling of plant-based products with names that include the names of dairy foods such as ''milk,'' ''cultured milk,'' ''yogurt,'' and ''cheese.'' The information will inform our development of an approach to the labeling of plant-based products that consumers may substitute for dairy foods. We asked that comments be submitted by November 27, 2018.

We have received requests for a 120-day extension of the comment period for the notice. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful responses to the questions that appeared in the notice requesting data and other evidence in support of answers.

We have considered the requests and are extending the comment period for another 60 days, until January 28, 2019. We believe that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying any potential further action on these important issues.

Dated: November 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25347 Filed 11–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 21, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0572. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

OMB Control Number 0910–0572—Extension

FDA's regulations governing the content and format of labeling for human prescription drug and biological products were revised in the **Federal Register** of January 24, 2006 (71 FR 3922) (the 2006 labeling rule) to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors because of misunderstood or incorrectly applied drug information.

Currently, § 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include a ''Highlights of Prescribing Information'' section. The ''Highlights'' section provides a concise extract of the most important information required under § 201.57(c) (the Full Prescribing Information (FPI)), as well as certain additional information important to prescribers. Section 201.57(b) requires a table of contents to

prescribing information entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that, within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57)

New drug product applicants must: (1) Design and create prescription drug labeling containing ''Highlights,'' ''Contents,'' and FPI; (2) test the designed labeling (*e.g.,* to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on the projected data used in the January 24, 2006, final rule, FDA estimates that it will take applicants approximately 2,327 hours to design, test, and submit prescription drug labeling to FDA as part of a NDA or a BLA under the revised regulations. Currently, approximately 406 applicants submit approximately 541 new applications (NDAs and BLAs) to FDA annually, totaling 1,258,907 hours.

In the **Federal Register** of July 20, 2018 (83 FR 34596), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. One comment encouraged the use of ''provider-neutral language'' in specific regulations. The second comment discussed the distribution of package inserts for prescription drugs via paper labeling. Because these comments do not apply to the regulations associated with the information collection, we have not addressed them here.

Our estimate of the burden for the information collection is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response	Total hours
Labeling Requirements in §§ 201.56 and 201.57	406	1.332	541	2,327	1,258,907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates may not sum due to rounding.

Our estimated burden for the information collection reflects an overall increase of 602,503 hours and a corresponding increase of 345 records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25352 Filed 11–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has been renewed.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Phone: (202) 795–7697; Fax: (202) 691–2102; Email: *ACBTSA@hhs.gov*.

SUPPLEMENTARY INFORMATION: ACBTSA is a non-discretionary Federal advisory committee. ACBTSA is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities related to the safety of blood, blood products, tissues, and organs. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation.

To carry out its mission, the ACBTSA provides advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

On September 25, 2018, the Secretary approved for the ACBTSA charter to be renewed. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on October 9, 2018. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until October 9, 2020.

A copy of the ACBTSA charter is available on the Committee's website at *https://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/advisory-committee/charter/index.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *www.facadatabase.gov*.

Dated: October 19, 2018.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability.

[FR Doc. 2018–25374 Filed 11–20–18; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.

Date: December 14, 2018.

Time: 9:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive; Suite 7189, Bethesda, MD 20892, 301–827–7911, *lindsay.garvin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 15, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25354 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Health and Aging Trends.

Date: December 3, 2018.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Room 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *firthkm@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 15, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25351 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of R35 Research Program Award.

Date: December 3–4, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, Virginia Ballroom A & B, 1900 Diagonal Rd, Alexandria, VA 22314.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3226, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *Jimok.kim@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Biomarkers Discovery in Parkinsonism.

Date: December 3, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3205, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *Joel.saydoff@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research

Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 14, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25355 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Conference Grants in Support of Heart, Lung, and Blood Research.

Date: December 11–12, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7296, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Stephanie J. Webb, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892, 301–287–7332, *stephanie.webb@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 15, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25353 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chronic Neurodegenerative Diseases.

Date: December 11, 2018.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 15, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25356 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2019 Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award a single source grant to the Community Anti-Drug Coalitions of America (CADCA).

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award $500,000 (total costs) for up to five years to CADCA for the National Anti-Drug Coalitions Training and Workforce Development Grant. Under this initiative, CADCA will provide training to state and community prevention leaders, including members of anti-drug community coalitions from around the country who are committed to addressing the evolving needs of the behavioral health field, and promote workforce development. Training and workforce development activities supported through this grant include SAMHSA's Prevention Day, the CADCA National Leadership Forum, and CADCA's Mid-Year Training Institute. These activities aim to disseminate knowledge and transfer state-of-the-art information, assisting state and community leaders in developing and implementing evidence-based programs, practices, and policies aligned with the 21st Century Cures Act, the Comprehensive Addition and Recovery Act, the President's Commission on combating drug addiction and the opioid crisis, and other national substance abuse prevention goals, outcomes, and efforts, including underage drinking prevention. This is not a formal request for applications. Assistance will be provided only to CADCA based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SP–19–002.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 516 of the Public Health Services Act, as amended.

Justification

Eligibility for this award is limited to CADCA. The purpose of this grant to provide training and workforce development for thousands of members of community coalitions dedicated to preventing substance abuse through a national leadership workforce development and training event. CADCA is the only national organization that has special expertise and unique broad, national-level experience in working with community anti-drug coalitions. For more than 22 years, coalitions and coalition leadership have turned to CADCA to obtain the assistance they need to implement, operate, and sustain effective local community anti-drug strategies. CADCA will take advantage of the resources of multiple agencies located throughout the federal, state and

local governments, philanthropies, and universities to bring the best available knowledge, information, and technology to local community anti-drug coalitions working to prevent and reduce drug use among the youth of America. CADCA is the only identified organization with the required experience and national reach to over 5,000 identified anti-drug coalitions across the country. Significant investments were made over the years to support this program with outstanding results. CADCA has long been recognized in communities as well as states throughout the nation for the technical support it has provided to anti-drug coalitions. As such, it is uniquely qualified and positioned to carry out the requirements of this announcement.

Contact: Odessa Crocker, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857; telephone: (240) 276–1078; email: *Odessa.Crocker@samhsa.hhs.gov*.

Dated: November 15, 2018.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2018–25349 Filed 11–20–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0792]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0035

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for a collection of information regarding: 1625–0035, Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159); without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before December 21, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2018–0792] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov*. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email: dhsdeskofficer@omb.eop.gov*.

(2) *Mail:* OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov*. Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an ICR to OMB, OIRA, requesting an extension of its approval for a collection of the following information: 1625–0035, Title 46 CFR Subchapter Q Lifesaving, Electrical, Engineering and Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159) without change.

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2018–0792], and must be received by December 21, 2018

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0035.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (83 FR 45267, September 6, 2018) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collections.

Information Collection Request

Title: Title 46 CFR Subchapter Q: Lifesaving, Electrical, Engineering and

Navigation Equipment, Construction and Materials & Marine Sanitation Devices (33 CFR part 159).

OMB Control Number: 1625–0035.

Summary: This information is used by the Coast Guard to ensure that regulations governing specific types of safety equipment, material and Marine Sanitation Devices (MSDs) installed on commercial vessels and pleasure craft are met. Manufacturers are required to submit drawings, specifications, and laboratory test reports to the Coast Guard before any approval is given.

Need: Title 46 U.S.C. 2103, 3306, 3703, and 4302 authorize the Coast Guard to establish safety equipment and material regulations. Title 46 CFR parts 159 to 164 prescribe these requirements. Title 33 U.S.C. 1322 authorizes the Coast Guard to establish MSD regulations. Title 33 CFR part 159 prescribes these rules. NVIC 8–01 (Chg 3) prescribes the standards for navigation equipment. This information is used to determine whether manufacturers are in compliance with Coast Guard regulations. When the Coast Guard approves any safety equipment, material or MSD for use on a commercial vessel or pleasure craft, the manufacturer is issued a Certificate of Approval.

Forms: CGHQ–10030, Certificate of Approval.

Respondents: Manufacturers of safety equipment, materials and marine sanitation devices.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 118,594 hours to 114,586 hours a year due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: November 14, 2018.

James D. Roppel,

Acting Chief, U.S. Coast Guard, Office of Information Management.

[FR Doc. 2018–25268 Filed 11–20–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0052]

Agency Information Collection Activities; Revision of a Currently Approved Collection; Application for Naturalization

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

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration

(USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information or new collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until January 22, 2019.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0052 in the body of the letter, the agency name and Docket ID USCIS–2008–0025. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0025;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0025 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov*.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Naturalization.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–400; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS uses the information gathered on Form N–400 to make a determination as to a respondent's eligibility to naturalize and become a U.S. citizen.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–400 (paper) is 567,314 and the estimated hour burden per response is 12 hours; the estimated total number of respondents for the information collection N–400 (electronic) is 214,186 and the estimated hour burden per response is 5 hours; and the estimated total number of respondents for the information collection Biometrics is 778,000 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 8,788,958.00 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $346,768,927.50.

Dated: November 15, 2018.

Samantha L Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2018–25345 Filed 11–20–18; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2018–N141; FXES11140800000–189–FF08EVEN00]

Habitat Conservation Plan for Seven Species in the Santa Clara River Watershed; Categorical Exclusion for Foothill Feeder Inspection and Maintenance Activities, Los Angeles County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from Metropolitan Water District of Southern California for an incidental take permit under the Endangered Species Act. The permit would authorize take of the federally endangered unarmored threespine stickleback, arroyo toad, the federally threatened California red-legged frog, and non-listed Santa Ana sucker, western spadefoot, two-striped garter snake, and western pond turtle incidental to otherwise lawful activities associated with the inspection and maintenance of the Foothill Feeder water conveyance pipeline in the draft habitat conservation plan prepared for the project. We invite public comment.

DATES: Written comments should be received on or before December 21, 2018.

ADDRESSES:

To obtain documents: You may download a copy of the draft habitat conservation plan and draft low-effect screening form and environmental action statement at *http://www.fws.gov/ventura/,* or you may request copies of the documents by U.S. mail (below) or by phone (see **FOR FURTHER INFORMATION CONTACT**).

To submit written comments: Please send us your written comments using one of the following methods:

- *U.S. mail:* Send your comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Facsimile:* Fax your comments to 805–644–3958.

FOR FURTHER INFORMATION CONTACT: Chris Dellith, Fish and Wildlife Biologist, 805–677–3308 (phone), or at the Ventura address in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: We have received an application for an incidental take permit (ITP) pursuant to section 10(a)(1)(B) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant has developed a draft habitat conservation plan (HCP) for the project that includes measures to mitigate and minimize impacts to seven covered species: the federally endangered unarmored threespine stickleback (*Gasterosteus aculeatus williamsoni*), a fish, and the arroyo toad (*Anaxyrus californicus*); the federally threatened California red-legged frog (*Rana draytonii*); and the non-listed Santa Ana sucker (*Catostomus santaanae*), a fish; western spadefoot (*Spea hammondii*), a toad; two-striped garter snake (*Thamnophis hammondii*); and western pond turtle (*Emys marmorata*). (The non-listed Santa Ana sucker (*Catostomus santaanae*) is federally listed as threatened outside of the area covered in the habitat conservation plan.) The permit would authorize take of any of these species incidental to otherwise lawful activities associated with the Foothill Feeder Inspection and Maintenance Activities HCP. We invite public comment on the application, the draft HCP, draft low-effect screening form, and environmental action statement.

Background

The unarmored threespine stickleback was listed by the Service as endangered on October 13, 1970 (35 FR 16047). The arroyo toad was listed by the Service as endangered on December 16, 1994 (59 FR 64859). The California red-legged frog was listed by the Service as threatened on May 23, 1996 (61 FR 25813). The Santa Ana sucker was listed by the Service as threatened, outside of the area covered by the draft HCP, on April 12, 2000 (65 FR 19686). The western spadefoot is currently under the Service's review for listing pursuant to the ESA (80 FR 37568). The two-striped garter snake is not federally listed, nor is it being considered for listing pursuant to the ESA at this time. The western pond turtle is currently under the Service's review for listing pursuant to the ESA (80 FR 19259). Section 9 of the ESA and its implementing regulations prohibit the take of fish or wildlife species listed as endangered or threatened. ''Take'' is defined under the ESA to include the following activities: ''[T]o harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the ESA, we may issue permits to authorize incidental take of listed species. ''Incidental take'' is defined by the ESA as take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are in the Code of Federal Regulations (CFR) at 50 CFR 17.32 and 17.22, respectively. Under the ESA, protections for federally listed plants differ from the protections afforded to federally listed animals. Issuance of an incidental take permit also must not jeopardize the existence of federally listed fish, wildlife, or plant species. The permittees would receive assurances under our ''No Surprises'' regulations ((50 CFR 17.22(b)(5) and 17.32(b)(5)) regarding conservation activities for the unarmored threespine stickleback, arroyo toad, California red-legged frog, Santa Ana sucker, western spadefoot, two-striped garter snake, and western pond turtle.

Applicant's Proposed Activities

The applicant has applied for a permit for incidental take of the unarmored threespine stickleback, arroyo toad, California red-legged frog, Santa Ana sucker, western spadefoot, two-striped garter snake, and western pond turtle. Take is likely to occur in association with activities necessary to inspect and maintain the Foothill Feeder water

conveyance pipeline. The covered area consists of approximately 22 river miles, within the Santa Clara River watershed, of cottonwood-willow, transitional riparian, alluvial sage scrub, oak woodland, upland scrub, and aquatic habitat, which provides suitable habitat for the unarmored threespine stickleback, arroyo toad, California red-legged frog, Santa Ana sucker, western spadefoot, two-striped garter snake, and western pond turtle. The covered area has no designated critical habitat for the covered species. The HCP includes measures to minimize take of the covered species in the form of injury and mortality. Mitigation for unavoidable take of the species consists of creating, restoring, and enhancing up to 40 acres of cottonwood-willow, transitional riparian, alluvial sage scrub, oak woodland, upland scrub, and aquatic habitat.

Our Preliminary Determination

The Service made a preliminary determination that issuance of the incidental take permit is neither a major Federal action that will significantly affect the quality of the human environment within the meaning of section 102(2)(C) of NEPA (42 U.S.C. 4321 *et seq.*), nor will it individually or cumulatively have more than a negligible effect on the species covered in the HCP. The Service considers the effects of the taking of the covered species to be minor because project activities resulting in incidental take of the covered species would occur infrequently (approximately every 5 years over a period of several weeks), the applicant has proposed a series of measures to avoid and minimize impacts to the covered species, and the applicant has committed to creating, restoring, and enhancing up to 40 acres of occupied or otherwise suitable habitat for the covered species within the Santa Clara River watershed. Therefore, based on this preliminary determination, the permit qualifies for a categorical exclusion under NEPA.

Public Comments

If you wish to comment on the permit application, draft HCP, and associated documents, you may submit comments by one of the methods in **ADDRESSES**.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: November 13, 2018.

Stephen P. Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2018–25397 Filed 11–20–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G]

Draft Environmental Impact Statement for the Little River Band Trust Acquisition and Casino Project, Township of Fruitport, Muskegon County, Michigan

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of availability.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA) as lead agency, with the Township of Fruitport, County of Muskegon, Little River Band of Ottawa Indians (Tribe), Federal Highway Administration, and the U.S. Environmental Protection Agency (EPA), serving as cooperating agencies, intends to file a Draft Environmental Impact Statement (DEIS) with the EPA in connection with the Tribe's application for transfer into trust by the United States of approximately 60 acres for gaming and other purposes to be located the Township of Fruitport, Muskegon County, Michigan. This notice also announces that the DEIS is now available for public review and that a public hearing will be held to receive comments on the DEIS.

DATES: Written comments on the DEIS must arrive within 45 days after EPA publishes its Notice of Availability in the **Federal Register**. The date and location of the public hearing on the DEIS will be announced at least 15 days in advance through a notice to be published in local newspaper, The Muskegon Chronicle, and online at *www.littlerivereis.com*.

ADDRESSES: You may mail or hand-deliver written comments to Mr. Timothy LaPointe, Midwest Regional Director, Bureau of Indian Affairs, Midwest Region, Norman Pointe II Building, 5600 West American Boulevard, Suite 500, Bloomington, Minnesota 55347. Please include your name, return address, and the caption: ''DEIS Comments, Little River Band Trust Acquisition and Casino Project,'' on the first page of your written comments. See the **SUPPLEMENTARY INFORMATION** section of this notice for addresses where the DEIS is available for review.

FOR FURTHER INFORMATION CONTACT: Mr. Felix Kitto, Regional Environmental Protection Specialist, Division of Environmental, Facilities, Safety and Cultural Resource Management (DEFSCRM), Bureau of Indian Affairs, Midwest Region, Norman Pointe II Building, 5600 West American Boulevard, Suite 500, Bloomington, Minnesota 55347; phone: (612) 725–4597; email: *felix.kitto@bia.gov*. Information is also available online at *www.littlerivereis.com*.

SUPPLEMENTARY INFORMATION: Public review of the DEIS is part of the administrative process for the evaluation of the Tribe's application to the BIA for the Federal trust acquisition of approximately 60 acres in the Township of Fruitport, Muskegon County, Michigan, upon which the Tribe proposes to develop a casino, hotel, parking, and other supporting facilities. A Notice of Intent was published in the **Federal Register** on September 21, 2015, as well as published in The Muskegon Chronicle. The BIA held a public scoping meeting for the project on October 15, 2015, at Fruitport Middle School, 3113 East Pontaluna Road, Fruitport, Michigan 49415.

Background: The Tribe's Proposed Project consists of the following components: (1) The transfer of an approximately 60-acre property from fee to trust status; (2) issuance of a Secretarial Determination by the Secretary of the Interior (Secretary) under Section 20 of the Indian Gaming Regulatory Act (IGRA) that gaming on the project site would be in the best interest of the Tribe and not detrimental to the surrounding community (25 U.S.C. 2719 (b)(1)(A)); and (3) development of the trust parcel and adjacent land owned by the Tribe, totaling approximately 86.5 acres, with a variety of uses including a casino, hotel, conference center, parking, and other supporting facilities. The proposed casino-hotel resort would include a hotel, a convention center, several restaurant facilities, and parking facilities. Access to the project site would be provided via two driveways: One along Harvey Street and one along East Ellis Road. Five service driveways,

not for public use, would be located on East Ellis Road.

The following alternatives are considered in the DEIS: (1) Proposed Project; (2) Reduced Intensity Alternative; (3) Non-Gaming Alternative; (4) Custer Site Alternative and (5) No Action/No Development. Environmental issues addressed in the DEIS include geology and soils, water resources, air quality, biological resources, cultural and paleontological resources, socioeconomic conditions (including environmental justice), transportation and circulation, land use, public services, noise, hazardous materials, aesthetics, cumulative effects, and indirect and growth-inducing effects.

Locations where the DEIS is available for review: The DEIS will be available for review at the Fruitport Public Library located at 47 Park St., Fruitport, Michigan 49415, and online at *www.littlerivereis.com*. To obtain a compact disk copy of the DEIS, please provide your name and address in writing to Mr. Felix Kitto, Bureau of Indian Affairs, Midwest Regional Office. Contact information is listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual paper copies of the DEIS will be provided only upon payment of applicable printing expenses by the requestor for the number of copies requested.

Public comment availability: Comments, including names and addresses of respondents, will be available for public review at the BIA address shown in the **ADDRESSES** section, during regular business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment that your personal identifying information be withheld from public review, the BIA cannot guarantee that this will occur.

Authority: This notice is published pursuant to Sec. 1503.1 of the Council of Environmental Quality Regulations (40 CFR parts 1500 through 1508) and Sec. 46.305 of the Department of the Interior Regulations (43 CFR part 46), implementing the procedural requirements of the NEPA of l969, as amended (42 U.S.C. 4371, *et seq.*), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.

Dated: November 9, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–25411 Filed 11–20–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/A0A501010.999900 253G]

Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Campo Wind Energy Project, San Diego, California

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of intent.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), as lead agency, with the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation (Tribe) as a cooperating agency, intends to gather information necessary for preparing an Environmental Impact Statement (EIS) for the proposed Campo Wind Project, located on the Campo Indian Reservation (Reservation) in southeastern San Diego County, approximately 60 miles east of San Diego, California. Construction of the Campo Wind Project is subject to BIA approval of a lease and sublease, which, as proposed, is a major Federal action under the National Environmental Policy Act of 1969 (NEPA), as amended. A brief description of the proposed action is provided below in the **SUPPLEMENTARY INFORMATION** section. This notice also announces a public scoping meeting to identify potential issues, concerns, and alternatives to be considered in the EIS. The scoping process will include notice to the public and Federal, State, local, and Tribal agencies of the proposed action.

DATES: Written comments on the scope and implementation of this proposal must arrive by 11:59 p.m. on December 21, 2018. The date and location of the public hearing on the EIS will be announced at least 15 days in advance through a notice to be published in local newspapers (The San Diego Union Tribune and The San Diego Business Journal) and online at: *www.campowind.com*.

ADDRESSES: The public may mail or hand-carry written comments to Ms. Amy Dutschke, Regional Director, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825. You may also submit comments through email to Mr. Dan (Harold) Hall, Acting Chief, Division of Environmental, Cultural Resource Management and Safety, Bureau of Indian Affairs, at *harold.hall@bia.gov*. More information can be found in the **SUPPLEMENTARY INFORMATION** section of this notice.

Please include the commenter's name, title, return address, and ''EIS Scoping Comments, Campo Wind Project, San Diego County, California,'' on the first page of the written comments. The scoping meeting will be held at Campo Indian Reservation Tribal Hall, 36190 Church Road (BIA Road 10), Campo, California 91906.

FOR FURTHER INFORMATION CONTACT: Mr. Dan (Harold) Hall Acting Chief, Division of Environmental, Cultural Resource Management and Safety, Bureau of Indian Affairs, by telephone at (916) 978–6041, or by email at *harold.hall@bia.gov*.

SUPPLEMENTARY INFORMATION:

Project Description

BIA approval is required for a lease and sublease to build and operate a commercial wind power generation facility capable of generating up to 252 megawatts (MW) of electricity.

The project would include the generation of up to 252 MW consisting of up to 60 turbines. The project study area covers approximately 2,200 acres on the Campo Indian Reservation. The total area that would be disturbed by the project would be substantially less. The turbines proposed for the project would range from 2.5 MW to 4.2 MW in maximum output rating per turbine, tubular steel towers, with a rotor diameter of approximately 450 feet, a hub height of approximately 361 feet, and a total height of turbine (highest point) of approximately 586 feet. Each turbine would be set on a concrete foundation. Turbines would be connected by an underground electrical collection system to a project collector substation. The collector substation would be sited on approximately 2 acres and would consist of a graveled, fenced area containing transformer and switching equipment and an area for vehicle parking. A new 230 kV overhead generation transmission line would be constructed, on the Campo Indian Reservation and partially outside on private lands, from the project collector substation on the Reservation to a San Diego Gas & Electric (SDG&E) substation/switchyard that would be constructed on private lands adjacent to the Sunrise Powerlink northeast of the Reservation. The SDG&E substation/switchyard and related transmission line improvements will be subject to approval by the County of San Diego,

California, Public Utilities Commission (CPUC) and the BIA. Other required facilities, all located within the Reservation, would include: Up to three permanent meteorological towers; temporary material laydown areas during construction; temporary staging and construction trailer areas; an operations and maintenance building; underground cabling; telecommunications; new access roads and improvements to portions of existing roads; and a temporary concrete batch plant. The wind power generation facility would operate year-round for a minimum of 25 years.

The EIS will analyze the potential environmental impacts of the construction and operation of a proposed wind generation facility, including access roads, a collector substation, as well as a substation/switchyard and transmission facilities. The EIS will be prepared in accordance with NEPA (42 U.S.C. 4321 *et seq.*); the Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500–1508); Department of the Interior regulations (43 CFR part 46); and the BIA NEPA Handbook (59 IAM 3–H) and will also be compliant with the California Environmental Quality Act in accordance with Public Resources Code section 21083.7. A reasonable range of alternatives to the proposed action including a no-action alternative, will be analyzed in the EIS. The range of issues and alternatives included will be based on comments and information received during the scoping process. This notice initiates the public scoping process to identify alternatives and relevant issues associated with the proposed project.

Directions for Submitting Public Comments

During the public scoping meetings, the public may submit written and verbal comments. Verbal comments given at the scoping meetings will have the same merit as written comments and will be addressed equally. The public may mail or hand-carry written comments to Ms. Amy Dutschke, Regional Director, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825. Please include the commenter's name, title, return address and ''EIS Scoping Comments, Campo Wind Project, San Diego County, California,'' on the first page of the written comments.

Public Availability of Comments

Comments, including names and addresses of respondents, will be available for public review at the BIA address shown in the **ADDRESSES** section of this notice, during business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Individual respondents may request confidentiality. If a commenter wishes us to withhold commenter's name and/or address from public review or from disclosure under the Freedom of Information Act, the commenter must state this prominently at the beginning of the written comment. Such requests will be honored to the extent allowed by the law, however there is a possibility that the comment(s) may be made publicly available at any time.

Authority

This notice is published in accordance with sections 1501.7 (Scoping), 1506.6 (Public involvement), and 1508.22 (Notice of Intent) of the CEQ Regulations (40 CFR parts 1500 through 1508) and section 46.305 of the Department of the Interior Regulations (43 CFR part 46), implementing the procedural requirements of NEPA, as amended (42 U.S.C. 4321 *et seq.*), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs by 209 DM 8.

Dated: November 9, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–25412 Filed 11–20–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19X.LLAK930000.L13100000.DS0000]

Notice of Intent To Prepare an Integrated Activity Plan and Environmental Impact Statement for the National Petroleum Reserve in Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In accordance with the Naval Petroleum Reserves Production Act of 1976, as amended, the Bureau of Land Management (BLM) Alaska State Office, Anchorage, Alaska, intends to prepare a new Integrated Activity Plan and Environmental Impact Statement (IAP/EIS) for BLM-managed lands within the National Petroleum Reserve in Alaska (NPR–A). By this notice, the BLM is announcing the beginning of the Environmental Impact Statement (EIS) scoping process to solicit public comments and identify issues.

DATES: Comments on relevant issues that will influence the scope of the EIS for the NPR–A IAP/EIS project may be submitted in writing until January 7, 2019. The BLM will also provide opportunities for public participation during scoping meetings with appropriate public notice. The date(s) and location(s) of scoping meetings will be announced in advance through local media, newspapers, and the BLM website at: *www.blm.gov/alaska.*

In order to be considered for the Draft IAP/EIS, all comments must be received prior to the close of the 45-day scoping period. Federal, State or local agencies, or tribes who are interested in serving as a cooperating agency for the development of the IAP/EIS are asked to submit such requests to the BLM.

ADDRESSES: You may submit comments on issues related to the proposed NPR–A IAP/EIS project by any of the following methods:

- *Online: http://www.blm.gov/alaska/NPR-A-IAP-EIS.*
- *Fax:* (907) 271–5479.
- *Mail:* NPR–A IAP/EIS Scoping Comments, 222 West 7th Avenue, Mailstop #13, Anchorage, AK 99513.

The 2013 IAP/EIS ROD can be downloaded from the BLM's website at *www.blm.gov/alaska,* and you can view hard copies at the BLM Alaska Public Information Center (''Public Room''), Arctic District Office, 222 University Avenue, Fairbanks, Alaska, and at the BLM Alaska Public Information Center (''Public Room''), Alaska State Office, 222 West 8th Avenue, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Stephanie Rice; Planning and Environmental Coordinator, 907–271–3202, *srice@blm.gov.* You may also request to be added to the mailing list. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This notice initiates the public scoping process for the EIS. Comments regarding management decisions, resources to be addressed, and issues for analysis will assist the BLM in defining the proposed actions and alternatives for the NPR–A IAP/EIS.

The Naval Petroleum Reserves Production Act (42 U.S.C. 6501), as amended, excludes the NPR–A from the application of Section 202 of the Federal Land Policy and Management Act (43 U.S.C. 1701), as amended, which is the

basis for the BLM's Resource Management Plans. The BLM conducts planning within the NPR–A with an IAP. The BLM complies with all applicable laws in the preparation of the IAP, including the National Environmental Policy Act, the Endangered Species Act, Marine Mammal Protection Act, and the National Historic Preservation Act.

Purpose and Need for Action

The BLM is developing a new IAP/EIS to determine the appropriate management of all BLM-managed lands in the NPR–A in a manner consistent with existing statutory direction and Secretarial Order 3352. Secretarial Order 3352 directs the development of a schedule to ''effectuate the lawful review and development of an IAP for the NPR–A that strikes an appropriate balance of promoting development while protecting surface resources.'' The Naval Petroleum Reserves Production Act, as amended, and its implementing regulations require oil and gas leasing in the NPR–A and the protection of surface values consistent with exploration, development and transportation of oil and gas.

Proposed Action

The BLM will be preparing a new IAP/EIS, which is intended to supersede the 2013 IAP/EIS ROD and, depending on the alternative selected, may supersede the 2008 Colville River Special Area Management Plan, as amended by the 2013 IAP/EIS ROD.

Lead and Cooperating Agencies

The BLM is the lead agency for the IAP/EIS. The BLM has extended invitations to participate as cooperating agencies to the U.S. Fish and Wildlife Service, the National Marine Fisheries Service, the State of Alaska, the North Slope Borough, the National Park Service, the Bureau of Ocean Energy Management, and the U.S. Geological Survey.

Responsible Official

The Secretary of the Interior is the responsible official.

Nature of Decision To Be Made

Consistent with the Naval Petroleum Reserves Production Act, the IAP/EIS will address a narrower range of multiple use management than a resource management plan (*e.g.,* it will not contemplate opening lands to hard rock or coal mining). The IAP/EIS will include: A consideration of a range of alternatives that make lands available for leasing; an examination of current special area boundaries; and, a consideration of new or revised lease stipulations and best management practices. The IAP/EIS would also ensure that the BLM's land management will provide the opportunity, subject to appropriate conditions developed through a National Environmental Policy Act (NEPA) process, to construct pipelines and other necessary infrastructure to bring oil and gas resources from offshore or adjacent leases to the Trans-Alaska Pipeline System or a future gas pipeline from the North Slope. The IAP/EIS would also consider the potential for a road system connecting communities across the North Slope.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the IAP/EIS. The purpose of the public scoping process is to determine the management decisions and resources to be addressed and the issues for analysis. The BLM will work collaboratively with interested parties to identify the management decisions best suited to local, regional, and national needs and concerns.

The BLM must receive all comments by the end of the scoping comment period to be included in the scoping report. The most useful comments are substantive comments that address the following topics: Areas available for leasing, special area boundaries, lease stipulations and best management practices, and resource issues to be analyzed.

You may submit written comments on management decisions, resources to be addressed, and issues for analysis to the BLM at any of the public scoping meetings, or you may use any of the methods listed in the **ADDRESSES** section above. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. Although you may ask the BLM to withhold your personal identifying information from public review, the BLM cannot provide any guarantees that it will be able to do so.

Authority: 40 CFR 1501.7.

Ted A. Murphy,

Acting State Director, Alaska.

[FR Doc. 2018–25336 Filed 11–20–18; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF JUSTICE

[OLP Docket No. 168]

Supplemental Information Regarding Arizona Capital Counsel Mechanism

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: This notice advises the public that the State of Arizona has provided additional information about its capital counsel mechanism, and solicits public comment on that supplemental information.

DATES: Written and electronic comments must be submitted on or before January 7, 2019. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. OLP 168'' on all electronic and written correspondence. The Department encourages that all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. Paper comments that duplicate the electronic submission should not be submitted. Individuals who wish to submit written comments may send those to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section immediately below.

FOR FURTHER INFORMATION CONTACT: Laurence Rothenberg, Deputy Assistant Attorney General, Office of Legal Policy, U.S. Department of Justice, 950 Pennsylvania Avenue NW, Washington, DC 20530; telephone (202) 532–4465.

SUPPLEMENTARY INFORMATION: Chapter 154 of title 28, United States Code, provides special procedures for federal habeas corpus review of cases brought by prisoners in State custody who are subject to capital sentences. The special procedures may be available to a State only if the Attorney General of the United States has certified that the State has established a qualifying mechanism for the appointment, compensation, and payment of reasonable litigation expenses of competent counsel in State postconviction proceedings for indigent capital prisoners. 28 U.S.C. 2261, 2265; 28 CFR part 26.

On November 16, 2017, the Department of Justice, Office of Legal Policy published a notice in the **Federal Register**, 82 FR 53529, advising the public of Arizona's request for certification, dated April 18, 2013, and requesting public comment regarding

that request. The Department also sent a letter to Arizona, dated November 16, 2017, asking whether the State wished to supplement or update its request. Arizona responded in a letter dated November 27, 2017. The Department, on December 27, 2017, published a second notice in the **Federal Register**, 82 FR 61329, which advised the public that the State had submitted additional information and provided additional time for public comment.

Following the receipt of public comments, the Department sent a letter dated June 29, 2018, to Arizona requesting that the State provide answers to a number of questions that had arisen during the Department's review of the comments, and inviting response to any other matters raised in the comments. This notice advises the public that the State of Arizona submitted additional information in response, in a letter dated October 16, 2018, and solicits public comment on that supplemental information. The correspondence with Arizona, including its letter of October 16, 2018, may be viewed at *https://www.justice.gov/olp/pending-requests-final-decisions*.

Following the Department's transmission of its letter of June 29, 2018 to Arizona, and again following Arizona's transmission of its responsive letter of October 16, 2018 to the Department, a commenter on Arizona's request for certification requested that the Department provide an opportunity for additional public comment to allow response to the new information in Arizona's letter. This notice provides an opportunity for such public comment.

Dated: November 13, 2018.

Beth A. Williams,

Assistant Attorney General.

[FR Doc. 2018–25333 Filed 11–20–18; 8:45 am]

BILLING CODE 4410–BB–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 6 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: See the **SUPPLEMENTARY INFORMATION** section for individual meeting times and dates. All meetings are Eastern time and ending times are approximate:

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Sherry Hale, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *hales@arts.gov,* or call 202/682–5696.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of July 5, 2016, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

The upcoming meetings are:

Literature (review of applications): This meeting will be closed.

Date and time: December 17, 2018; 1:00 p.m. to 3:00 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 17, 2018; 2:30 p.m. to 4:30 p.m.

Literature (review of applications): This meeting will be closed.

Date and time: December 18, 2018; 1:00 p.m. to 3:00 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 18, 2018; 11:30 a.m. to 1:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 18, 2018; 2:30 p.m. to 4:30 p.m.

Media Arts (review of applications): This meeting will be closed.

Date and time: December 19, 2018; 11:30 a.m. to 1:30 p.m.

Dated: November 16, 2018.

Sherry Hale,

Staff Assistant, National Endowment for the Arts.

[FR Doc. 2018–25376 Filed 11–20–18; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0236]

Memorandum of Understanding Between the U.S. Nuclear Regulatory Commission and the Wyoming Department of Environmental Quality

AGENCY: Nuclear Regulatory Commission.

ACTION: Memorandum of understanding; issuance.

SUMMARY: This notice is announcing that, effective on September 30, 2018, the U.S. Nuclear Regulatory Commission (NRC or Commission) and the State of Wyoming, Department of Environmental Quality (WYDEQ), entered into a Memorandum of Understanding (MOU) for the purpose of establishing a regulatory process for the completion of decommissioning of five uranium mill tailing sites and the termination of the associated uranium mill licenses located within the State of Wyoming.

DATES: The MOU was issued on September 30, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0236 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking website: Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0236. Address questions about dockets in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly available documents online in the ADAMS Public Document collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ''Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the Wyoming Department of Environmental Quality to Establish a Process for the Completion of Decommissioning of Five Uranium Mill Tailing Sites and the Termination of the Associated Uranium Mill Licenses Located within the State of

Wyoming,'' is available electronically in ADAMS under Accession Number ML18165A254.

• NRC's Public Document Room (PDR): The public may examine and purchase copies of public documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Stephen Poy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–7135; email: *Stephen.Poy@nrc.gov*.

SUPPLEMENTARY INFORMATION: Effective September 30, 2018, the NRC and the WYDEQ (collectively referred to as the Agencies) entered into a MOU for the purpose of establishing a regulatory process for the completion of decommissioning of five uranium mill tailing sites and the termination of the associated uranium mill licenses located within the State of Wyoming. This MOU pertains to the Agencies' roles in the decommissioning and eventual termination of the license for the following five uranium mill sites:

1. Anadarko Bear Creek located in Converse County, Wyoming (NRC License No. SUA–1310, Docket No. 040–08452)
2. Pathfinder Lucky Mc located in Fremont County, Wyoming (NRC License No. SUA–672, Docket No. 040–02259)
3. Western Nuclear Split Rock located approximately 2 miles from Jeffrey City, Wyoming (NRC License SUA–56, Docket No. 040–01162)
4. Umetco Minerals Corporation Gas Hills East located in Natrona, County Wyoming (NRC License No. SUA–648, Docket No. 040–00299)
5. ExxonMobil Highlands located approximately 25 miles north of Douglas, Wyoming (NRC License No. SUA–1139, Docket No. 040–08102)

The five licenses were transferred to the State of Wyoming on September 30, 2018, when the NRC discontinued, and the State of Wyoming assumed, regulatory authority over the management and disposal of byproduct material as defined in 11e.(2) of the Atomic Energy Act of 1954, as amended (the Act), and a subcategory of source material or ores involved in the extraction or concentration of uranium or thorium milling in the State in accordance with the agreement authorized by Section 274b. of the Act (83 FR 48905; September 28, 2018). The MOU documents completed NRC actions related to the decommissioning process for each of the sites and delineates specific actions, on a site-by-site basis, that the NRC and the State of Wyoming will take to verify completion of the decommissioning and license termination for these sites. The MOU stipulates that any decision made by the NRC for the five uranium mill sites prior to the discontinuation of the NRC's regulatory authority in Wyoming will be appropriately recognized by the NRC as meeting all applicable standards and requirements when reviewing the Completion Review Report. A Completion Review Report is required to be submitted by the State of Wyoming to the NRC, prior to license termination of a uranium mill site, for review and approval to adequately ensure public health and safety. Upon termination of each license, the site may be transferred, customarily, to the U.S. Department of Energy for long-term care and surveillance.

The NRC and WYDEQ will cooperate fully with each other to carry out this MOU and its intent of ensuring protection of public health, safety, and the environment in accordance with all governing laws and regulations.

Dated at Rockville, Maryland, this 15th day of November, 2018.

For the Nuclear Regulatory Commission.

Daniel S. Collins,

Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–25367 Filed 11–20–18; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2019–17]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 26, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2019–17; *Filing Title:* Notice of United States Postal

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Service of Filing a Functionally Equivalent Global Expedited Package Services 9 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* November 15, 2018; *Filing Authority:* 39 CFR 3015.5*; Public Representative:* Curtis E. Kidd; *Comments Due:* November 26, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–25377 Filed 11–20–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84604; File No. SR–CboeBZX–2018–077]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change To List and Trade Shares of the JPMorgan Inflation Managed Bond ETF of the J.P. Morgan Exchange-Traded Fund Trust Under Rule 14.11(i), Managed Fund Shares

November 15, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2018, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to list and trade shares of the JPMorgan Inflation Managed Bond ETF (the ''Fund'') of the J.P. Morgan Exchange-Traded Fund Trust (the ''Trust'' or the ''Issuer'') under Rule 14.11(i) (''Managed Fund Shares''). The shares of the Fund are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange.[3] The Fund will be an actively managed exchange-traded fund that seeks to maximize inflation protected total return. The Exchange submits this proposal in order to allow the Fund to hold Inflation Swaps and Other Derivatives, as each is defined below, in a manner that may not comply with Rule 14.11(i)(4)(C)(iv)(a),[4] Rule 14.11(i)(4)(C)(iv)(b),[5] and/or Rule 14.11(i)(4)(C)(v),[6] as further described below.[7] Otherwise, the Fund will comply with all other listing requirements on an initial and continued listing basis under Rule 14.11(i).

The Fund will be an actively managed fund. The Shares will be offered by the Trust, which was established as a Delaware statutory trust. J.P Morgan Investment Management, Inc. is the investment adviser (the ''Adviser'') and the administrator (''Administrator'') to the Fund. JPMorgan Chase Bank, N.A. is the custodian and transfer agent (''Custodian'' and ''Transfer Agent,'' respectively) for the Trust. JPMorgan Distribution Services, Inc. serves as the distributor (''Distributor'') for the Trust. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[8]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission originally approved BZX Rule 14.11(i) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018) and subsequently approved generic listing standards for Managed Fund Shares under Rule 14.11(i) in Securities Exchange Act Release No. 78396 (July 22, 2016), 81 FR 49698 (July 28, 2016) (SR–BATS–2015–100).

[4] Rule 14.11(i)(4)(C)(iv)(a) provides that ''there shall be no limitation to the percentage of the portfolio invested in such holdings; provided, however, that in the aggregate, at least 90% of the weight of such holdings invested in futures, exchange-traded options, and listed swaps shall, on both an initial and continuing basis, consist of futures, options, and swaps for which the Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other members or affiliates of the ISG or for which the principal market is a market with which the Exchange has a comprehensive surveillance sharing agreement, calculated using the aggregate gross notional value of such holdings.'' The Exchange is proposing that the Fund be exempt from this requirement only as it relates to the Fund's holdings in certain credit default swaps, interest rate swaps, and Inflation Swaps, as further described below.

[5] Rule 14.11(i)(4)(C)(iv)(b) provides that ''the aggregate gross notional value of listed derivatives based on any five or fewer underlying reference assets shall not exceed 65% of the weight of the portfolio (including gross notional exposures), and the aggregate gross notional value of listed derivatives based on any single underlying reference asset shall not exceed 30% of the weight of the portfolio (including gross notional exposures).'' The Exchange is proposing that the Fund would meet neither the 65% nor the 30% requirements of Rule 14.11(i)(4)(C)(iv)(b). Specifically, the Exchange is proposing that the Fund be exempt from this requirement as it relates to the Fund's holdings in listed derivatives, which include U.S. Treasury futures, Eurodollar futures, options on U.S. Treasuries and Treasury futures, credit default swaps, and certain Inflation Swaps and interest rate swaps, as further described below, which could constitute as much as 100% of the weight of the portfolio (including gross notional exposures) based on a single underlying reference asset.

[6] Rule 14.11(i)(4)(C)(v) provides that ''the portfolio may, on both an initial and continuing basis, hold OTC derivatives, including forwards, options, and swaps on commodities, currencies and financial instruments (*e.g.,* stocks, fixed income, interest rates, and volatility) or a basket or index of any of the foregoing, however the aggregate gross notional value of OTC derivatives shall not exceed 20% of the weight of the portfolio (including gross notional exposures).'' The Exchange is proposing that the Fund be exempt from this requirement as it relates to the Fund's holdings in OTC derivatives, which could constitute as much as 75% of the weight of the portfolio (including gross notional exposures).

[7] The Adviser, as defined below, notes that the Fund may by virtue of its holdings be issued certain equity instruments (''Equity Holdings'') that may not meet the requirements of Rule 14.11(i)(4)(C)(i). The Fund will not purchase such instruments and will dispose of such holdings as the Adviser determines is in the best interest of the Fund's shareholders. Such holdings will not constitute more than 10% of the Fund's net assets. The Adviser expects that the Fund will generally acquire such instruments through issuances that it receives by virtue of its other holdings, such as corporate actions or convertible securities.

[8] *See* Registration Statement on Form N–1A for the Trust, dated July 31, 2018 (File Nos. 333–191837 and 811–22903). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement. The Commission has issued an order granting certain exemptive relief to the Trust under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (''1940 Act'') (the ''Exemptive Order'').

Continued

Rule 14.11(i)(7) provides that, if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.[9] In addition, Rule 14.11(i)(7) further requires that personnel who make decisions on the investment company's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable investment company portfolio. Rule 14.11(i)(7) is similar to Rule 14.11(b)(5)(A)(i), however, Rule 14.11(i)(7) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. The Adviser is not a registered broker-dealer, but is affiliated with multiple broker-dealers and has implemented and will maintain ''fire walls'' with respect to such broker-dealers regarding access to information concerning the composition and/or changes to the Fund's portfolio. In addition, Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with another broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

The Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code of 1986, as amended.

JPMorgan Inflation Managed Bond ETF

According to the Registration Statement, the Fund will be an actively managed exchange-traded fund that will seek to maximize inflation protected total return. The Fund is designed to protect the total return generated by its fixed income holdings from inflation risk. Total return includes income and capital appreciation. The Fund seeks to achieve its investment objective by investing, under Normal Market Conditions,[10] at least 80% of its net assets in Bonds,[11] Inflation Hedging Instruments, and Other Derivatives, as defined below. The Fund will gain exposure to U.S. dollar-denominated bonds primarily through investing directly in Bonds. Up to 10% of the Fund's total assets may be invested in securities rated below investment grade (junk bonds). Junk bonds are rated in the fifth or lower rated categories (for example, BB+ or lower by Standard & Poor's Ratings Services and Ba1 or lower by Moody's). The Fund may also use the following instruments to gain exposure to credit or interest rates: credit default swaps,[12] interest rate swaps,[13] Eurodollar futures,[14] U.S. Treasury futures,[15] options on U.S. Treasury Futures,[16] and options on U.S. Treasuries [17] (collectively, ''Other Derivatives'').

The Fund will attempt to mitigate the inflation risk of the Fund's exposure to Bonds primarily through the use of either OTC or listed inflation swaps (''Inflation Swaps''),[18] which are

Investment Company Act Release No. 31990 (February 9, 2016) (File No. 811–22903).

[9] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[10] As defined in Rule 14.11(i)(3)(E), the term ''Normal Market Conditions'' includes, but is not limited to, the absence of trading halts in the applicable financial markets generally; operational issues causing dissemination of inaccurate market information or system failures; or force majeure type events such as natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[11] For purposes of this proposal, the term ''Bond'' includes only the following U.S. dollar denominated instruments issued by the U.S. Government or its agencies and instrumentalities, a domestic or a foreign corporation or a municipality: corporate bonds, U.S. government and agency debt securities (excluding Treasury Inflation Protected Securities (''TIPS''), which, as described below, may be held by the Fund in order to attempt to mitigate inflation risk), asset-backed securities, and mortgage-related and mortgage-backed securities. Mortgage-related and mortgage-backed securities may be structured as collateralized mortgage obligations (agency and non-agency), stripped mortgage-backed securities (interest-only or principal-only), commercial mortgage-backed securities, mortgage pass-through securities, collateralized mortgage obligations, adjustable rate mortgages, convertible bonds and zero-coupon obligations. The Exchange notes that the Fund's holdings in Bonds will meet the requirements of Rule 14.11(i)(4)(C)(ii)(a)–(e) related to the fixed income securities portion of the Fund, including the requirement that non-agency, non-GSE, and privately-issued mortgage-related and other asset-backed securities components of a portfolio shall not account, in the aggregate, for more than 20% of the weight of the fixed income portion of the portfolio. The Fund will generally hold investment-grade Bonds, but may hold up to 10% of its net assets in Bonds that are not investment-grade at the time of purchase.

[12] *See* supra notes 4 and 5. Credit default swaps held by the Fund will be traded on a U.S. Swap Execution Facility registered with the Commodity Futures Trading Commission. The Fund may hold up to 10% of its net assets in credit default swaps that are not investment-grade at the time of purchase.

[13] *See* supra notes 4, 5, and 6. Interest rate swaps held by the Fund may include listed swaps, centrally cleared OTC swaps, or non-cleared OTC swaps. The Fund will attempt to limit counterparty risk in non-listed and non-cleared OTC swap contracts by entering into such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis. To the extent that the Fund holds listed interest rate swaps, all such listed swaps held by the Fund will be traded on a U.S. Swap Execution Facility registered with the Commodity Futures Trading Commission.

[14] *See* supra note 5.

[15] *See* supra note 5.

[16] *See* supra note 5.

[17] *See* supra notes 4, 5, and 6. Options on U.S. Treasuries held by the Fund may include listed or OTC options. The Fund will attempt to limit counterparty risk in non-listed and non-cleared OTC options contracts by entering into such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis.

[18] *See* supra notes 4, 5, and 6. The Fund will attempt to limit counterparty risk in non-listed and non-cleared OTC swap contracts by entering into such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis. To the extent that the Fund holds listed Inflation Swaps, all such listed Inflation Swaps held by the Fund will be traded on a U.S. Swap Execution Facility registered with the Commodity Futures Trading Commission. Inflation Swaps held by the Fund will reference the Consumer Price Index For All Urban Consumers (CPI–U).

managed on an active basis. Additionally, the Fund may also attempt to mitigate inflation risk through investing in TIPS (collectively, with Inflation Swaps, ''Inflation Hedging Instruments''). The Exchange is proposing to allow the Fund to hold up to 100% of the weight of its portfolio (including gross notional exposure) in Inflation Swaps and Other Derivatives, collectively, in a manner that may not comply with Rules 14.11(i)(4)(C)(iv)(a),[19] 14.11(i)(4)(C)(iv)(b),[20] and/or 14.11(i)(4)(C)(v).[21]

The Fund's investments, including derivatives, will be consistent with the 1940 Act and the Fund's investment objective and policies and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage).[22] That is, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2Xs and 3Xs) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A). The Fund will only use those derivatives included in the defined terms Inflation Swaps and Other Derivatives. The Fund's use of derivative instruments will be collateralized. In addition to the use described above, the Fund will also use derivative holdings for efficient portfolio management, profit and gain for the Fund, interest rate hedging, and managing credit risk.

Other Investments

Under Normal Market Conditions, the Fund may also invest up to 20% of its net assets in the following: One or more ETFs,[23] money market mutual funds, including affiliated money market mutual funds, bank obligations, common and preferred stock, convertible securities (including contingent convertible securities), loan assignment and participations, commitments to purchase loan assignments, auction rate securities, commercial paper, common stock warrants and rights, custodial receipts, inverse floating rate instruments, non-ETF investment company securities, securities issued by real estate investment trusts, repurchase and reverse repurchase agreements, short-term funding agreements, structured investments, synthetic variable rate instruments, trust preferred securities, when-issued securities, delayed delivery securities, forward commitments, pay-in-kind securities, and deferred payment securities (collectively, excluding ETFs, ''20% OTC Instruments''). The Fund may also engage in securities lending.

The Exchange represents that, except for the exceptions to BZX Rule 14.11(i)(4)(C) described above, the Fund's proposed investments will satisfy, on an initial and continued listing basis, all of the generic listing standards under BZX Rule 14.11(i)(4)(C) (the ''Generic Listing Rules'') and all other applicable requirements for Managed Fund Shares under Rule 14.11(i). The Trust is required to comply with Rule 10A–3 under the Act for the initial and continued listing of the Shares of the Fund. In addition, the Exchange represents that the Shares of the Fund will comply with all other requirements applicable to Managed Fund Shares including, but not limited to, requirements relating to the dissemination of key information such as the Disclosed Portfolio, net asset value (''NAV''), and the Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, firewalls, and the information circular, as set forth in Exchange rules applicable to Managed Fund Shares and the orders approving such rules. At least 100,000 Shares will be outstanding upon the commencement of trading.

Moreover, all of the ETFs, futures contracts, and listed options contracts, and certain of the Equity Holdings held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[24] Additionally, the Exchange or FINRA, on behalf of the Exchange, are able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine (''TRACE'') and municipal securities reported to the Municipal Securities Rulemaking Board's (the ''MSRB'') Electronic Municipal Market Access system. FINRA also can access data obtained from the MSRB relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. All statements and representations made in this filing regarding the description of the portfolio or reference assets, limitations on portfolio holdings or reference assets, dissemination and availability of index, reference asset, and intraday indicative values, and the applicability of Exchange rules specified in this filing shall constitute continued listing requirements for the Fund. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12.

Availability of Information

As noted above, the Fund will comply with the requirements for Managed Fund Shares related to Disclosed Portfolio, Net Asset Value, and the Intraday Indicative Value. Additionally, the intra-day, closing and settlement prices of exchange-traded portfolio assets, including common stock, preferred stock, warrants, rights, exchange-listed Equity Holdings, ETFs, options, and futures, will be readily available from the securities exchanges and futures exchanges trading such securities and futures, as the case may be, automated quotation systems, published or other public sources, or online information services such as Bloomberg or Reuters. Intraday price quotations on both listed and OTC swaps, TIPS, 20% OTC Instruments, and fixed income instruments are

[19] *See* supra note 4.

[20] *See* supra note 5.

[21] *See* supra note 6.

[22] The Fund will include appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of a fund, including a fund's use of derivatives, may give rise to leverage, causing a fund to be more volatile than if it had not been leveraged. The Fund's investments in derivative instruments will be made in accordance with the 1940 Act and consistent with the Fund's investment objective and policies. To mitigate leveraging risk, the Fund will segregate or earmark liquid assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board and in accordance with the 1940 Act (or, as permitted by applicable regulations, enter into certain offsetting positions) to cover its obligations under derivative instruments. These procedures have been adopted consistent with Section 18 of the 1940 Act and related Commission guidance. *See* 15 U.S.C. 80a–18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128 (April 27, 1979); Dreyfus Strategic Investing, Commission No-Action Letter (June 22, 1987); Merrill Lynch Asset Management, L.P., Commission No-Action Letter (July 2, 1996).

[23] For purposes of this proposal, the term ''ETF'' includes Portfolio Depositary Receipts, Index Fund Shares, and Managed Fund Shares as defined in Rule 14.11(b), (c), and (i), respectively, and their equivalents on other national securities exchanges.

[24] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay or in real-time for a paid fee. Trade price and other information relating to Municipal Securities is available through the MSRB. Price information for cash equivalents will be available from major market data vendors. The Disclosed Portfolio will be available on the issuer's website free of charge. The Fund's website includes a form of the prospectus for the Fund and additional information related to NAV and other applicable quantitative information. Information regarding market price and trading volume of the Shares will be continuously available throughout the day on brokers' computer screens and other electronic services. Quotation and last sale information on the Shares will be available through the Consolidated Tape Association. Information regarding the previous day's closing price and trading volume for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for listed options contracts cleared by the Options Clearing Corporation will be available via the Options Price Reporting Authority. Trading in the Shares may be halted for market conditions or for reasons that, in the view of the Exchange, make trading inadvisable. The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. The Exchange has appropriate rules to facilitate trading in the shares during all trading sessions.

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (4) the risks involved in trading the Shares during the Pre-Opening [25] and After Hours Trading Sessions [26] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Fund. Members purchasing Shares from the Fund for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

In addition, the Information Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV calculation time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's website.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [27] in general and Section 6(b)(5) of the Act [28] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest in that the Shares will meet each of the initial and continued listing criteria in BZX Rule 14.11(i) except that the Fund may not comply with Rules 14.11(i)(4)(C)(iv)(a),[29] 14.11(i)(4)(C)(iv)(b),[30] and/or 14.11(i)(4)(C)(v).[31] The Exchange believes that the liquidity in the Treasury futures,[32] Eurodollar futures,[33] and TIPS [34] markets mitigates the concerns that Rule 14.11(i)(4)(C)(iv)(b) is intended to address and that such liquidity would help prevent the Shares from being susceptible to manipulation. Further, the Exchange believes that for listed swaps, including credit default swaps, interest rate swaps, and Inflation Swaps, the price transparency and surveillance performed by the applicable swap execution facility would similarly act to mitigate the risk of manipulation of the Shares. The Exchange also believes that the size of the inflation swaps market,[35] which would include all of the Inflation Swaps that the Fund intends to invest in, also mitigates manipulation concerns relating to both listed and OTC Inflation Swaps held by the Fund.[36]

As it relates to addressing the policy concerns that Rule 14.11(i)(4)(C)(v) is intended to address, which provides that the notional value of OTC derivatives shall not exceed 20% of the weight of the portfolio (including gross notional exposures), in an effort to minimize exposure to potentially illiquid and manipulable derivatives contracts, the Exchange notes that the inflation swap market,[37] which would include all of the listed and OTC Inflation Swaps that the Fund intends to invest in, is large and liquid, which the Exchange believes further mitigates the concerns which Rule 14.11(i)(4)(C)(v) is intended to address. The Exchange also notes that the Fund will attempt to limit counterparty risk in non-cleared OTC swap contracts, OTC Inflation Swaps, and interest rate swaps, by entering into

[25] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[26] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[27] 15 U.S.C. 78f.

[28] 15 U.S.C. 78f(b)(5).

[29] *See* supra note 4.

[30] *See* supra note 5.

[31] *See* supra note 6.

[32] In 2017, there were approximately 744 million Treasury futures contracts traded.

[33] In 2017, there were approximately 367 million Eurodollar futures contracts traded.

[34] In 2017, there were approximately $17 billion worth of TIPS traded at primary dealers on a daily basis.

[35] For purposes of this discussion, the term ''inflation swaps market'' means any swap contract that references either a measure of inflation, an inflation index, or an instrument designed to transfer inflation risk from one party to another.

[36] According to publicly available numbers from LCH. Clearnet Limited, which clears both listed and OTC swaps, as of October 26, 2018, there had been approximately $637 billion in U.S. dollar-denominated inflation swaps traded year-to-date, which would include the Inflation Swaps that the Fund intends to invest in, cleared through their platform alone.

[37] *See* supra note 35.

such contracts only with counterparties the Adviser believes are creditworthy and by limiting the Fund's exposure to each counterparty. The Adviser will monitor the creditworthiness of each counterparty and the Fund's exposure to each counterparty on an ongoing basis. Further, the Exchange notes that notional principal never changes hands in such swaps transactions, and it is a theoretical value used to base the exchanged payments. A more accurate representation of the swaps value in order to monitor total counterparty risk would be the mark-to market value of the swap since inception, which the Adviser generally expects to remain below 15% of the Fund's net assets.

As it relates to the requirement in Rule 14.11(i)(4)(C)(iv)(a) that at least 90% of the weight of the listed derivatives portion of the portfolio be in listed derivatives for which the Exchange may obtain information via ISG or for which the principal market is a market with which the Exchange has a comprehensive surveillance sharing agreement, the Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Additionally, all of the listed instruments that would not meet this requirement would nevertheless have a primary market that is a swap execution facility that is registered with and under the regulatory oversight of the CFTC.[38]

Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares. All of the futures contracts, listed options, ETFs, and certain of the listed Inflation Swaps, listed credit default swaps, Equity Holdings, and listed interest rate swaps held by the Fund will trade on markets that are a member of ISG or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange, FINRA, on behalf of the Exchange, or both will communicate regarding trading in the Shares and the underlying futures contracts, listed options, ETFs, and certain of the listed Inflation Swaps, credit default swaps, Equity Holdings, and listed interest rate swaps held by the Fund with the ISG, other markets or entities who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[39] The Exchange, FINRA, on behalf of the Exchange, or both may obtain information regarding trading in the Shares and the underlying futures contracts, listed options, ETFs, and certain of the listed Inflation Swaps, credit default swaps, Equity Holdings, and listed interest rate swaps held by the Fund via the ISG from other markets or entities who are members or affiliates of the ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[40] Additionally, the Exchange or FINRA, on behalf of the Exchange, may access, as needed, trade information for certain fixed income instruments reported to TRACE and municipal securities reported to the MSRB. FINRA also can access data obtained from the MSRB relating to municipal bond trading activity for surveillance purposes in connection with trading in the Shares. The Exchange has a policy prohibiting the distribution of material non-public information by its employees.

The Exchange notes that the Fund will meet and be subject to all other requirements of the Generic Listing Rules and other applicable continued listing requirements for Managed Fund Shares under Rule 14.11(i), including those requirements regarding the Disclosed Portfolio and the requirement that the Disclosed Portfolio and the NAV will be made available to all market participants at the same time,[41] Intraday Indicative Value,[42] suspension of trading or removal,[43] trading halts,[44] disclosure,[45] and firewalls.[46] Further, at least 100,000 Shares will be outstanding upon the commencement of trading.[47]

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional actively-managed exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) by order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2018–077 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2018–077. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[38] The Exchange represents that not all CFTC registered swap execution facilities are members or affiliates of members of the ISG.

[39] *See* supra note 23 [sic].

[40] *See* supra note 23 [sic].

[41] *See* Rules 14.11(i)(4)(A)(ii) and 14.11(i)(4)(B)(ii).

[42] *See* Rule 14.11(i)(4)(B)(i).

[43] *See* Rule 14.11(i)(4)(B)(iii).

[44] *See* Rule 14.11(i)(4)(B)(iv).

[45] *See* Rule 14.11(i)(6).

[46] *See* Rule 14.11(i)(7).

[47] *See* Rule 14.11(i)(4)(A)(i).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2018–077 and should be submitted on or before December 12, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[48]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25344 Filed 11–20–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84603; File No. SR–NYSEAMER–2018–48]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Modify the NYSE American Options Fee Schedule

November 15, 2018.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 8, 2018, NYSE American LLC (the ''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE American Options Fee Schedule (''Fee Schedule''). The Exchange proposes to implement the fee change effective November 8, 2018. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule, effective November 8, 2018, to eliminate obsolete charges. Specifically, the Exchange proposes to remove now obsolete references to fees for Mini Options and Binary Return Derivatives (''ByRDS''), and to modify its Royalty Fees to remove products that the Exchange is no longer licensed to trade.

The Exchange adopted fees for Mini Options in 2013, when Mini Options were first listed.[4] In the intervening years, the Exchange ceased adding new Mini-Option series, and eventually there were no Mini-Options trading on the Exchange. Thus, the Exchange proposes to remove from the Fee Schedule as obsolete all references to Mini-Options and associated fees.[5] Given that the Exchange is removing Mini Options, it proposes to further streamline the Fee Schedule by removing as superfluous the designation of ''Standard'' as to delineate non-Mini Options and to make any related conforming changes to maintain appropriate grammar, sentence structure, etc.[6]

The Exchange listed ByRDs for trading in 2016,[7] but ceased adding new series earlier this year, and no longer has any ByRDs available for trading. Thus, the Exchange proposes to remove from the Fee Schedule as obsolete all references to ByRDs and associated fees/credits as well as to make necessary conforming changes, including deleting note 5 to Section I.A. and re-numbering the balance of the notes to this section to maintain clarity and consistency.[8]

Section I.K. of the Fee Schedule contains a table that sets forth the Royalty Fees that the Exchange charges market participant for trades in proprietary products for which the Exchange has a license, namely: Mini Nasdaq 100 Index (NDX), Nasdaq 100 Index (MNX), the Russell Index (RUT), and KBW Bank Index (BKX). The Exchange proposes to delete the table and to instead reference a $0.10 per contract Royalty Fee for BKX, as this product continues to be licensed to the Exchange.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed modifications to the Fee

[48] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See, e.g.,* Securities Exchange Act Release No. 69298 (April 4, 2013), 78 FR 21464 (April 10, 2013) (NYSEMKT–2013–24).

[5] *See* proposed Fee Schedule, Table of Contents, Key Terms and Definitions, Sections I.B., I.C., I.F., I.I., I.J., I.L., II and III. The Exchange proposes to hold Section I.B., which currently sets forth fees for Mini Options, as Reserved.

[6] *See* proposed Fee Schedule, Table of Contents, Key Terms and Definitions, Sections I.A.-I.G., I.I–I.J., I.L., II and III.

[7] The Exchange adopted ByRDs in 2007 and re-launched trading in ByRDs in March, 2016. See Securities Exchange Act Release No. 56251 (August 14, 2007), 72 FR 46523 (August 20, 2007)(SR–Amex–2004–27) (Order approving listing of Fixed Return Options (''FROs'')); see also Securities Exchange Act Release Nos. 71957 (April 16, 2014), 79 FR 22563 (April 22, 2014) (SR–NYSEMKT–2014–06) (Order approving name change from FROs to Binary Return Derivatives (ByRDs) and re-launch of these products, with certain modification, and amending Obvious Errors rules to include ByRDs); 77014 (February 2, 2016), 81 FR 6566 (February 8, 2016) (SR–NYSEMKT–2016–16) (immediate effectiveness filing amending amend certain of rules related to ByRDs).

[8] *See* proposed Fee Schedule, Table of Contents, Sections I.A., I.H., I.M, and III.C., note 1. The Exchange proposes to hold Section I.H., which currently sets the Early Adopter Specialist [in ByRDs], as Reserved.

[9] *See* proposed Fee Schedule, Section I.K.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

Schedule, including removing obsolete references to products that the Exchange no longer offers or licenses, together with their associated fees, are reasonable, equitable, and not unfairly discriminatory because the changes provides clarity to the Fee Schedule, and does not affect any current activity by any ATP Holder. Relatedly, the proposed modifications to streamline the text of the Fee Schedule, including by removing the modifier ''Standard'' to delineate on non-Mini Option, would likewise add clarity and transparency to the Fee Schedule making it easier for market participants to navigate and comprehend.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[12] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the proposed change is meant to add clarity and transparency to the Fee Schedule to the benefit of all market participants that trade on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [13] of the Act and subparagraph (f)(2) of Rule 19b–4 [14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEAMER–2018–48 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2018–48. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2018–48 and should be submitted on or before December 12, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

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[12] 15 U.S.C. 78f(b)(8).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84599; File No. SR–CboeEDGA–2018–017]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend the Exchange's Fee Schedule Applicable to its Equities Trading Platform

November 15, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 1, 2018, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to amend the Exchange's fee schedule applicable to its equities trading platform.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule, effective November 1, 2018, to (i) amend transaction fee rates, (ii) amend the definition for fee code MT, (iii) adopt new Add and Remove Volume Tiers, (iv) amend the threshold under the RMPT/RMPL Tier, and (v) adopt a new Routing Tier.

Transaction Fee Changes

Orders That Add Liquidity

In securities priced at or above $1.00, the Exchange currently charges a fee of $0.00080 per share for Displayed and Non-Displayed orders that add liquidity. All Displayed and Non-Displayed orders in securities priced below $1.00 that add liquidity are free. The Exchange first proposes to increase this transaction fee and assess a standard rate of $0.0030 per share for Displayed and Non-Displayed orders that add liquidity for securities at or above $1.00 that are appended with fee codes B, V, Y, 3, 4, RP, HA, DA, and DM. The Exchange notes that it is not proposing to increase the fee for Non-Displayed orders that add liquidity using Mid-Point Peg, which orders yield fee code MM. All Displayed and Non-Displayed orders in securities priced below $1.00 that add liquidity would continue to be free.

Orders That Remove Liquidity

In securities priced at or above $1.00, the Exchange currently provides a rebate of $0.00040 per share for Displayed orders that remove liquidity (*i.e.,* yields fee codes N, W, 6 and BB) and provides free executions for Non-Displayed orders that remove liquidity (*i.e.,* yields fee codes DR, DT, HR, and MT). All Displayed and Non-Displayed orders in securities priced below $1.00 that remove liquidity are currently free, with the exception of orders that yield fee codes HR and MT, which result in a fee of 0.05% of dollar value.

With respect to Displayed orders priced at or above $1.00 that remove liquidity, the Exchange proposes to increase the per share rebate from $0.00040 to $0.0024 (*i.e.,* yields fee codes N, W, 6, or BB). All Displayed orders in securities priced below $1.00 would continue to be free.

With respect to Non-Displayed orders priced at or above $1.00 that remove liquidity, the Exchange proposes to offer a $0.0024 per share rebate for Non-Displayed orders that remove liquidity using MidPoint Discretionary order not within discretionary range (*i.e.,* yields fee code DR).

With respect to the Non-Displayed orders priced below $1.00 that remove liquidity (*i.e.,* yields fee code HR) and removes liquidity using MidPoint Peg (*i.e.,* yields fee code MT [3]), the Exchange proposes to eliminate the current fee of 0.05% of dollar value and make these executions free, which will result in all Non-Displayed orders in securities priced below $1.00 being treated the same (*i.e.,* no fees or rebates assessed).

Fee Code MT

The Exchange also proposes to modify the definition of fee code MT. Currently, fee code MT is appended to all Non-Displayed orders that remove liquidity using Mid Point Peg order type.[4] The Exchange proposes to modify the types of orders that yield fee code MT, such that fee code MT will be appended to all orders that remove Mid-Point Peg Order liquidity (''Mid-Point Peg liquidity'') from EDGA, (*i.e.,* any order for which a Mid-Point Peg order that adds liquidity (fee code MM) is the contra). The Exchange notes that the proposed amended definition for the MT fee code is the same as the definition (*i.e.,* configuration) for the same fee code (MT) on its affiliate exchange, Cboe BYX Exchange, Inc.[5]

Add/Remove Volume Tiers

The Exchange next proposes to adopt an Add Volume Tier, Tier 1 and Remove Volume Tier, Tier 1 (under new footnote 7). Particularly, proposed Add Volume Tier 1 would provide a reduced fee of $0.0026 per share for members that add an ADAV of greater than or equal to 0.10% of the TCV [6] for orders that add liquidity yielding fee codes 3, 4, B, v and Y. The Exchange proposes to also add language in its Definitions section defining ''ADAV''. Specifically, ADAV shall mean average daily added volume calculated as the number of shares added per day.[7] The Exchange notes that the proposed definition of ADAV is similar to definitions at other Exchanges, such as its affiliate Exchange, Cboe BYX Exchange, Inc. (''BYX''). Additionally, BYX has a similar Add Volume Tiers that require members to reach ADAV thresholds of the TCV.[8] The Exchange believes the proposed change will encourage members to increase their liquidity on the Exchange.

The Exchange proposes to adopt Remove Volume Tier 1, which would provide an enhanced rebate of $0.0026 per share for members that (1) has an ADAV of greater than or equal to 0.20% of the TCV and (2) has a remove ADV [9] greater than or equal to 0.40% of the TCV for orders that remove liquidity yielding fee codes N, W, 6 and BB. The Exchange believes the proposed tier will encourage members to increase their liquidity on the Exchange. The Exchange also notes that other exchanges have similar volume tiers with similar requirements.[10]

The Exchange believes the proposed volume requirements under both Add and Remove Volume Tiers 1 are commensurate with the level of the incentives provided.

Amend RMPT/RMPL Tier

The Exchange currently offers a tier under footnote 1, the RMPT/RMPL Tier under which a Member receives a discounted fee of $0.0008 per share for orders yielding fee code PX where that Member meets certain required criteria.

[3] The Exchange is proposing to amend the definition of orders that yield fee code MT, as further described in this rule filing.

[4] *See* Cboe EDGA Rule 11.8(d). Mid-Point Peg Orders are non-displayed Market Orders or Limit Orders with an instruction to execute at the midpoint of the NBBO, or, alternatively, pegged to the less aggressive of the midpoint of the NBBO or one minimum price variation inside the same side of the NBBO as the order.

[5] *See* Cboe BYX Equities Exchange Fee Schedule, Fee Codes and Associated Fees, fee code MT.

[6] TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply. *See* Exchange's fee schedule.

[7] Like ADV (which means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange (or any subset thereof), ADAV will be calculated on a monthly basis. Additionally, as with ADV, the Exchange will exclude from its calculation of ADAV shares added, removed, or routed on any day that the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours, on any day with a scheduled early market close, and on the last Friday in June. A member will be able to aggregate ADAV (and ADV) with other Members that control, are controlled by, or are under common control with such Member).

[8] *See* Cboe BYX Exchange, Inc. Equities Exchange Fee Schedule, Footnote 1.

[9] ADV means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis. *See* Exchange's fee schedule.

[10] *See* Nasdaq BX, Inc. (''BX'') Rule 7018, Nasdaq BX Equities System Order Execution and Routing, which provides a credit for orders that meet thresholds relating to accessing liquidity and adding liquidity. *See also* Cboe BYX U.S. Equities Exchange Fee Schedule, Volume Tier 8 under Footnote 1.

Fee code PX is appended to orders that are routed using the RMPL routing strategy to a destination not covered by fee code PL, or are routed using the RMPT routing strategy, and are assessed a fee of $0.00120 per share on securities priced over $1.00, and a fee of 30% of the total dollar value on securities priced below $1.00. Under Tier 1, a Member is charged a discounted fee of $0.0008 per share for orders yielding fee code PX where they add or remove an ADV greater than or equal to 4,000,000 shares using the RMPT or RMPL [11] routing strategies (*i.e.,* yielding fee codes PA, PL, PT and PX). The Exchange proposes amend the ADV requirement of Tier 1 from greater or equal to 4,000,000 shares to 2,000,000 shares.

Adopt ROUT Tier

The Exchange proposes to also adopt a new routing tier for orders routed using the ROUT strategy [12] (''ROUT Tier''), under Footnote 1 of the Fees Schedule. Particularly, the Exchange proposes to offer a discounted fee of $0.0026 per share for orders yielding fee code RT where that Member meets certain required criteria. Fee code RT is appended to orders that are routed using the ROUT routing strategy, and are assessed a fee of $0.00280 per share on securities priced over $1.00, and a fee of 30% of the total dollar value on securities priced below $1.00. The Exchange proposes to provide that under ROUT Tier 1, a Member will be charged a discounted fee of $0.0026 per share for orders yielding fee code RT where the Member routes an ADV than or equal to 3,000,000 shares using routing strategy ROUT (*i.e.,* yielding fee codes RT and RX).[13] In connection the proposed changes, the Exchange proposes to also change the title of Footnote 1 from ''RMPT/RMPL Tiers'' to ''Routing Tiers'' to address both the RMPT/RMPL Tier and the new proposed ROUT Tier.

2. Statutory Basis

The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

The Exchange believes its proposal to increase rates for Non-Displayed and Displayed orders that add liquidity (other than orders that yield fee code MM) is reasonable because the Exchange must balance the cost of rebates for orders that remove liquidity (and as described above, the Exchange is increasing the rebates provided for orders that remove liquidity). Additionally, the Exchange notes that the proposed fee is similar to, and in line with, transaction fees assessed on other Exchanges.[14] Additionally the Exchange notes the proposed fee increase applies uniformly to members.

The Exchange believes the proposed increased rebate for Displayed orders that remove liquidity is reasonable, equitable and not unfairly discriminatory because it provides a higher rebate to members and is designed to further incentivize members to bring additional liquidity to the Exchange, thereby promoting price discovery and enhancing order execution opportunities for members. The Exchange believes the proposed changes are equitable and not unfairly discriminatory because they apply equally to all members. Furthermore, the Exchange's inverted fee structure would continue to incentivize liquidity takers since orders that remove liquidity would remain eligible for better pricing—including increased rebates for displayed orders and free executions for non-displayed orders—than orders that add liquidity and are charged a fee.

The Exchange believes the proposal to adopt a rebate for orders that remove liquidity using MidPoint Discretionary Orders not within discretionary range (*i.e.,* orders yielding fee code DR) is reasonable because it provides a rebate to members for these executions they were not otherwise receiving. Additionally, the Exchange notes the proposed rebate is the same as the rebate offered for Displayed orders that remove liquidity. The Exchange notes the proposed rule change applies uniformly to all members.

The Exchange believes the proposal to provide free executions for orders priced below $1.00 and yielding fee codes HR and MT is reasonable, because members will no longer be assessed any fees for these particular transactions. The Exchange also notes the proposed change results in all Non-Displayed orders in securities priced below $1.00 being treated the same (*i.e.,* no fees or rebates assessed). The proposed change also applies equally to all members.

The Exchange believes the proposed change to the definition for fee code MT is reasonable because orders that currently yield fee code MT (*i.e.,* Non-Displayed Mid-Point Peg orders that remove liquidity) will continue to receive free executions, as going forward they will be appended with either fee code HR (*i.e.,* Non-displayed orders that remove liquidity), if contra to any order that adds liquidity other than Mid-Point Peg orders, or MT (*i.e.,* an order that removes Mid-Point order liquidity), if contra to a Mid-Point Peg order that adds liquidity. Additionally, the proposed rule change is reasonable because all Displayed and Non-Displayed orders that remove a Non-Displayed Mid-Point Peg Order will also receive a free execution. The proposed rule change is equitable and not unfairly discriminatory because it applies to all members. Additionally, as noted above, the proposed definition of fee code MT is the same as the definition used on another exchange.[15]

The Exchange believes the proposal to adopt an Add and Remove Volume Tier, along with a ROUT Tier, is reasonable because it provides members an opportunity to receive a reduced fee or enhanced rebate, depending on the Tier. The Exchange additionally notes that volume-based discounts have been widely adopted by exchanges and are equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value of an exchange's market quality; (ii) associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns; and (iii) introduction of higher volumes of orders into the price and volume discovery processes. The proposed required criteria of the Volume Tiers are intended to incentivize Members to send additional orders to the Exchange in an effort to qualify for the reduce fee and enhanced rebate made available by the respective tiers. The Exchange also notes that increased volume on the Exchange provides greater trading opportunities for all market participants. As noted previously, the Exchange also believes the proposed required criteria under the Add and Remove Volume Tiers 1 and ROUT Tier are commensurate with the level of the incentives provided.

The Exchange believe that the amendment to the RMPL/RMPT Tier is reasonable and equitable because the amount of the discounted fee is not changing and because the amendment to the required criteria is designed to make it easier for market participants to

[11] *See* Cboe EDGA Rule 11.11(g)(13).

[12] *See* Cboe EDGA Rule 11.11(g)(3).

[13] Pursuant to the Fees Schedule, variable rates provided by tiers apply only to executions in securities priced at or above $1.00.

[14] *See e.g.,* NYSE Arca Equities, Fees and Charges, NYSE Arca Marketplace: Trade Related Fees and Credits.

[15] *See* Cboe BYX Equities Exchange Fee Schedule, Fee Codes and Associated Fees, fee code MT.

satisfy the tier and thus receive a discounted rate. The Exchange also believes notwithstanding the proposed change, RMPL/RMPT Tier 1 still attracts additional midpoint liquidity to the Exchange, resulting in increased price improvement opportunities for orders seeking an execution at the midpoint of the NBBO on the Exchange or elsewhere. The Exchange notes that routing through the Exchange is voluntary. The Exchange also believes that the proposed routing tier change is non-discriminatory because it applies uniformly to all members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Particularly, the proposed rates and rebates would apply uniformly to all members, and members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing venues to maintain their competitive standing in the financial markets. Further, excessive fees would serve to impair an exchange's ability to compete for order flow and members rather than burdening competition. Moreover, the proposed fee changes are designed to incentivize liquidity, which the Exchange believes will benefit all market participants by encouraging a transparent and competitive market. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and paragraph (f) of Rule 19b–4 thereunder.[17] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGA–2018–017 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeEDGA–2018–017. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of this filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGA–2018–017 and should be submitted on or before December 12, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25340 Filed 11–20–18; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84602; File No. SR–LCH SA–2018–005]

Self-Regulatory Organizations; LCH SA; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Amendment No. 1, Relating to a New Fee Incentive Scheme

November 15, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 31, 2018, Banque Centrale de Compensation, which conducts business under the name LCH SA (''LCH SA''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which Items have been prepared by LCH SA. On November 15, 2018, LCH SA filed Amendment No. 1 to the proposed rule change.[3] LCH SA filed the proposal pursuant to Section 19(b)(3)(A) of the Act,[4] and Rule 19b–4(f)(2) [5] thereunder, so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change will introduce a new fee incentive scheme

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, LCH SA added to Item II an additional description of the proposed fees.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(2).

for CDSClear client clearing activities applicable from October 31st, 2018.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, LCH SA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. LCH SA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is for LCH SA to introduce and specify a clearing fees incentive scheme for clients of CDSClear members, including volume based discounts, in order to encourage the growth of the CDSClear client clearing franchise.

Currently, CDSClear clearing members are charged a fee on their client clearing flows per EUR/USD million of gross notional cleared defined as follows:

VARIABLE FEE

Client Clearing (Per million gross notional cleared)					
EUR indices	EUR single names	Credit index options—EUR indices	US indices	US single names	Credit index option—US indices *
€4	€12	€20	$5	$17	[$20]

* Subject to regulatory approval.

The proposed incentive scheme defines a fee rebate based on volumes in order to make it more attractive for new buy side clients to select CDSClear services and/or CDSClear existing clients to clear more by reducing the marginal cost of clearing past pre-defined volumes thresholds as detailed hereinafter and below in Exhibit 5.

1. QUARTERLY CREDIT INDEX OPTION THRESHOLDS

Notional cleared (quarterly)	Fees
From €0 to €2bn	Full published variable fees apply.
From over €2bn to €10bn.	20% discount on published variable fees *(applicable only above €2bn)*.
Over €10bn	No further fees apply.

2. QUARTERLY CREDIT INDEX THRESHOLDS

Notional cleared (quarterly)	Fees
From €0 to €30bn	Full published variable fees apply.
Over €30bn	No further fees apply.

3. QUARTERLY CORPORATE SINGLE NAME THRESHOLDS

Notional cleared (quarterly)	Fees
From €0 to €4bn	Full published fees variable apply.
Over €4bn	No further fees apply.

The thresholds apply to quarterly notional cleared and the potential resulting rebate will be applied on the bill for the last month of the quarter.

The first quarterly notionals to be reviewed will be the Q4 2018 ones.

The proposed fee discount scheme will be effective until 31st December 2020.

Finally, the proposed incentive scheme will also exempt from clearing fees the registration of clients' positions at CDSClear resulting from the transfer of such positions from another CCP.

2. Statutory Basis

Section 17A(b)(3)(D) of the Act requires that the rules of a clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges.[6]

LCH SA has determined that the proposed fees are reasonable and appropriate to charge to offer and maintain CDSClear client clearing services.

In particular, LCH SA believes that the volume-based discounts for CDSClear client clearing activities have been set up at an appropriate level given the costs and expenses to LCH SA in providing such services.

LCH SA believes that imposing such clearing fees is consistent with the requirements of Section 17A of the Act[7] and the regulations thereunder applicable to it and in particular provides for the equitable allocation of reasonable fees, dues, and other charges among clearing members and market participants by ensuring that Members pay reasonable fees and dues for the services provided by LCH SA, within the meaning of Section 17A(b)(3)(D) of the Act.

B. Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act requires that the rules of a clearing agency not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[8] LCH SA does not believe that the proposed rule change would impose any burden on competition.

As noted above, LCH SA believes that the fees and related discounts have been set up at an appropriate level given the costs and expenses to LCH SA in offering and maintaining the relevant client clearing services.

Additionally, the fees and related discounts will apply equally to all clients of all clearing members of CDSClear.

Further, LCH SA does not believe that the proposed rule change would have a burden on competition because it does not adversely affect the ability of such Clearing Members or other market participants generally to engage in cleared transactions or to access clearing services.

C. Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. LCH SA will notify the Commission of any written comments received by LCH SA.

[6] 15 U.S.C. 78q–1(b)(3)(D).

[7] 15 U.S.C. 78q–1.

[8] 15 U.S.C. 78q–1(b)(3)(I).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and Rule 19b–4(f)(2)[10] thereunder because it establishes a fee or other charge imposed by LCH SA on its Clearing Members. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such proposed rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–LCH SA–2018–005 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–LCH SA–2018–005. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of LCH SA and on LCH SA's website at *https://www.lch.com/resources/rules-and-regulations/proposed-rule-changes-0*.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–LCH SA–2018–005 and should be submitted on or before December 12, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25342 Filed 11–20–18; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84601; File No. SR–CFE–2018–001]

Self-Regulatory Organizations; Cboe Futures Exchange, LLC; Notice of Filing of a Proposed Rule Change Regarding Minor Rule Violations

November 15, 2018.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 31, 2018 Cboe Futures Exchange, LLC (''CFE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change described in Items I, II, and III below, which Items have been prepared by CFE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. CFE also has filed this proposed rule change with the Commodity Futures Trading Commission (''CFTC''). CFE filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act (''CEA'')[2] on October 31, 2018.

[1] 15 U.S.C. 78s(b)(7).

[2] 7 U.S.C. 7a–2(c).

I. Self-Regulatory Organization's Description of the Proposed Rule Change

The Exchange proposes to amend its rules regarding the processing of minor rule violations. The scope of this filing is limited solely to the application of the proposed rule amendments to security futures that may be traded on CFE. Although no security futures are currently listed for trading on CFE, CFE may list security futures for trading in the future. The text of the proposed rule change is attached as Exhibit 4 to the filing but is not attached to the publication of this notice.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CFE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CFE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

CFE Rule 714 (Imposition of Fines for Minor Rule Violations) provides for the issuance of letters of caution or summary fines for specified types of minor CFE rule violations instead of addressing these violations through formal disciplinary proceedings. Each violation type under Rule 714 has a summary fine schedule that includes increasing monetary fines for subsequent violations by a party during a specified rolling time period and a referral of that party to the CFE Business Conduct Committee once that party has committed a certain number of violations within that rolling time period. The referral to the BCC is so that a panel of the BCC (''BCC Panel'') may determine whether or not to authorize the issuance of a statement of charges against the party and proceed with a formal disciplinary proceeding with regard to the matter.

CFE is making amendments to Rule 714 in conjunction with other rule amendments being made by CFE to its disciplinary rules, including to Rule 714, that are not required to be submitted to the Commission pursuant

to Section 19(b)(7) of the Act [3] and thus are not included as part of this rule change. One of these other rule amendments is to vest in CFE's Chief Regulatory Officer (''CRO'') instead of in a BCC Panel the authority to determine whether to issue a statement charges in a CFE disciplinary matter.

Since BCC Panels will no longer be determining whether to issue statements of charges, the proposed rule change deletes referral to the BCC from each of the summary fine schedules under Rule 714 that addresses violations of CFE rule provisions related to recordkeeping and reporting requirements. These summary fine schedules include the summary fine schedules under the following subparagraphs of Rule 714(f) which have the following titles and relate back to the following CFE rule provisions referenced in those titles:

(i) Rule 714(f)(i) relating to Failure to Include an Order Entry Operator ID with Order that is Submitted to the CFE System (CFE Rule 303A(a)), Improper Use of Order Entry Operator IDs (Rules 303A(b) and 303A(c)), and Failure to Comply with Issuance, Recordkeeping, and Reporting Requirements Related to Order Entry Operator IDs (Rule 303A(d));

(ii) Rule 714(f)(ii) relating to Failure to Identify Correct Customer Type Indicator Code in Order (CFE Rule 403(a)(x));

(iii) Rule 714(f)(iii) relating to Failure to Provide Correct Account Designation in Order (Rule 403(a)(xii));

(iv) Rule 714(f)(iv) relating to Failure to Comply with Order Form Preparation and Recordkeeping Requirements Relating to Orders Which Cannot Be Immediately Entered into the CFE System (Rule 403(b)) and Failure to Maintain Front-End Audit Trail Information for All Electronic Orders Entered into the CFE System, Including Order Modifications and Cancellations (Rule 403(c));

(v) Rule 714(f)(vi) relating to Failure to Comply with Notice Provisions for Position Accountability (CFE Rules 412A(c) and 412A(d));

(vi) Rule 714(f)(vii) relating to Failure to Comply with Reporting Requirements for Ownership and Control Reports and Reportable Positions (CFE Rules 412B(a), 412B(b), and 412B(c));

(vii) Rule 714(f)(viii) relating to Failure to Comply with Order Marking Requirement for Exchange of Contract for Related Position Transactions (CFE Rule 414(g)) and Failure to Comply with Recordkeeping Requirement for Exchange of Contract for Related Position Transactions (Rule 414(h));

(viii) Rule 714(f)(ix) relating to Failure to Comply with Exchange of Contract for Related Position Transaction Rule Provisions Relating to Authorized Reporter (Rule 414(i));

(ix) Rule 714(f)(x) relating to Failure to Comply with Exchange of Contract for Related Position Transaction Reporting Requirements (Rules 414(k) and 414(l));

(x) Rule 714(f)(xi) relating to Failure to Comply with Order Marking Requirement for Block Trades (CFE Rule 415(a)(i)(A)) and Failure to Comply with Recordkeeping Requirements for Block Trades (Rule 415(e));

(xi) Rule 714(f)(xiii) relating to Failure to Comply with Block Trade Rule Provisions Relating to Authorized Reporter (Rule 415(f));

(xii) Rule 714(f)(xiv) relating to Failure to Comply with Block Trade Reporting Requirements (Rules 415(h) and 415(i)); and

(xiii) Rule 714(f)(xv) relating to Failure to Provide Books and Records Within Designated Time Frame (CFE Rule 502 and Other CFE Rules Allowing CFE to Request Books and Records).

Regulatory staff already has the ability to proceed with a formal disciplinary proceeding whenever regulatory staff determines that any violation covered by Rule 714 is intentional, egregious, or otherwise not minor in nature. The proposed rule change also amends Rule 714(f) to clarify that regulatory staff may also proceed with a formal disciplinary proceeding if the number of recurring violations of a particular type covered by Rule 714 within the rolling time period for that type of violation warrants a formal disciplinary proceeding. Accordingly, with the proposed rule change, there will not be a need for a referral after a certain number of violations within the applicable rolling time period since regulatory staff may initiate a formal disciplinary proceeding for any violation covered by Rule 714 when circumstances warrant no matter the number of previous violations of that type.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Sections 6(b)(5),[5] 6(b)(6),[6] and 6(b)(7) [7] in particular in that it is designed:

- To prevent fraudulent and manipulative acts and practices;
- to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest;
- to have rules that provide that Exchange members and persons associated with Exchange members shall be appropriately disciplined for violation of the Act, the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction; and
- to provide a fair procedure for the disciplining of members and persons associated with members.

The proposed rule change is consistent with these provisions in that CFE believes that the proposed rule change provides an effective and efficient means of disciplining parties for certain types of minor rule violations that do not warrant formal disciplinary proceedings while also permitting regulatory staff to initiate formal disciplinary proceedings for these types violations when circumstances warrant.

B. Self-Regulatory Organization's Statement on Burden on Competition

CFE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act in that the proposed rule change will improve the efficiency and functioning of CFE's disciplinary process by providing greater flexibility to regulatory staff to determine when to initiate a formal disciplinary proceeding for any violation covered by Rule 714. Additionally, CFE believes that the proposed amendments are equitable and not unfairly discriminatory because the changes will apply equally to all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change will become operative on November 15, 2018. At any time within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule

[3] 15 U.S.C. 78s(b)(7).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78f(b)(6).

[7] 15 U.S.C. 78f(b)(7).

change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[8]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CFE–2018–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CFE–2018–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CFE–2018–001, and should be submitted on or before December 12, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25358 Filed 11–20–18; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78s(b)(1).

[9] 17 CFR 200.30–3(a)(73).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84600; File No. SR–CboeBYX–2018–014]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Make Permanent Exchange Rule 11.24, Which Sets Forth the Exchange's Pilot Retail Price Improvement Program

November 15, 2018.

I. Introduction

On July 30, 2018, Cboe BYX Exchange, Inc. (''BYX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to make permanent Exchange Rule 11.24, which sets forth the Exchange's pilot Retail Price Improvement Program. The proposed rule change was published for comment in the **Federal Register** on August 17, 2018.[3] On September 27, 2018, the Commission extended to November 15, 2018, the time period in which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.[4] The Commission received no comments on the proposed rule change. This order institutes proceedings under Section 19(b)(2)(B) of the Act[5] to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 11.24 to make permanent the Retail Price Improvement Program (the ''Program''), which sets forth the rules and procedures governing the program and is currently offered on a pilot basis.[6] The pilot is scheduled to expire upon the earlier of the approval of this proposed rule change or December 31, 2018.[7] According to the Exchange, the Program is designed to attract retail order flow and allow such order flow to receive potential price improvement.[8]

Under the Program, a class of market participant called a Retail Member Organization (''RMO'') is eligible to submit certain retail order flow (''Retail Orders'') to the Exchange. A User[9] is permitted to provide potential price improvement for Retail Orders[10] by submitting Retail Price Improvement (''RPI'') Orders, which are non-displayed orders that are priced at least $0.001 better than the best protected bid (''PBB'') or best protected offer (''PBO'') (''PBBO''), as such terms are defined in Regulation NMS, and that is identified as such.[11] After an RPI Order is submitted, the Exchange disseminates an indicator through its proprietary data feeds or through the Consolidated Tape Association/Consolidated Quotation Plan for Tape A and Tape B securities

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 83831 (August 13, 2018), 83 FR 41128 (''Notice'').

[4] *See* Securities Exchange Act Release No. 84297, 83 FR 49959 (October 3, 2018).

[5] 15 U.S.C. 78(s)(b)(2)(B).

[6] In November 2012, the Commission approved the Program on a pilot basis. *See* Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) (''RPI Approval Order'') (SR–BYX–2012–019).

[7] The Exchange implemented the Program on January 11, 2013, and has extended the pilot period five times. *See* Securities Exchange Act Release Nos. 71249 (January 7, 2014), 79 FR 2229 (January 13, 2014) (SR–BYX–2014–001); 74111 (January 22, 2015), 80 FR 4598 (January 28, 2015) (SR–BYX–2015–05); 76965 (January 22, 2016), 81 FR 4682 (January 27, 2016) (SR–BYX–2016–01); 78180 (June 28, 2016), 81 FR 43306 (July 1, 2016) (SR–BYX–2016–15); and 81368 (August 10, 2017), 82 FR 38960 (August 16, 2017) (SR–BYX–2017–18).

[8] *See* Notice, *supra* note 3 at 41128.

[9] A ''User'' is defined in Exchange Rule 1.5(cc) as any member or sponsored participant of the Exchange who is authorized to obtain access to the System.

[10] A ''Retail Order'' is defined in Exchange Rule 11.24(a)(2) as an agency order or riskless principal that meets the criteria of FINRA Rule 53250.03 that originates from a natural person and is submitted to the Exchange by a RMO, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any computerized methodology. *See* Exchange Rule 11.24(a)(2).

[11] *See* Notice, *supra* note 3 at 41128. As more fully set forth in the Notice, RPI Orders may be submitted with an explicit limit price, or an offset. RPI Orders submitted with an offset are similar to other peg orders in that the order is tied or ''pegged'' to a certain price, and would have its price automatically set and adjusted upon changes to the Protected NBBO. The offset is a predetermined amount by which the User is willing to improve the Protected NBBO, subject to a ceiling or floor price. The ceiling or floor price is the amount above or below which the User does not wish to trade. RPI Orders in their entirety (the buy or sell interest, the offset, and the ceiling or floor) will remain non-displayed.

and the Nasdaq UTP Plan for Tape C securities, known as the Retail Liquidity Identifier, indicating that such interest exists.[12] The Retail Liquidity Identifier reflects the symbol for the particular security and the side (buy or sell) of the RPI interest, but does not include the price or size of the RPI interest.[13]

To qualify as an RMO, a member organization must conduct a retail business or route retail orders on behalf of another broker-dealer.[14] A member organization must submit the following to the Exchange for approval: (i) An application form, (ii) supporting documentation, and (iii) an attestation that substantially all orders submitted as retail orders will qualify as such. The Program provides for an appeal process for a disapproved applicant, and a withdraw process for RMOs. RMOs must have written policies and procedures reasonably designed to assure that they will only designate orders as Retail Orders if all requirements of a Retail Order are met. RMOs could be disqualified if they submit Retail Orders that do not meet the requirements of Retail Orders. If disqualified, RMOs may appeal and reapply.

Under the Program, there are two types of Retail Orders. A Type 1 Retail Order will interact with only available contra-side RPI Orders and other price improving contra-side interest.[15] A Type 1 Retail Order will not interact with other available contra-side interest or route to away markets. The unexecuted portion of a Type 1 Retail Order will be immediately cancelled. A Type 2 Retail Order will interact first with available contra-side RPI Orders and price-improving liquidity, and then any remaining portion will be executed as an immediate-or-cancel order.[16] A Type 2-desiganted Retail Order can either be submitted as a BYX Only Order or an order eligible for routing.[17]

The Program provides that RPI Orders will be ranked and allocated according to price-time priority. Executions occur in price time priority. Any remaining unexecuted RPI interest remains available to interact with other incoming Retail Orders if such interest is at an eligible price.

A more detailed description of how the program operates, including but not limited to how a member organization may qualify an apply to become a RMO; the different types of Retail Orders; and priority and order allocation of RPI Orders is more fully set forth in the Notice.[18]

As part of the RPI Approval Order, the Exchange agreed to provide the Commission with a significant amount of data to assist the Commission's evaluation of the Program.[19] Specifically, the Exchange represented that it would ''produce data throughout the pilot, which will include statistics about participation, the frequency and level of price improvement provided by the Program, and any effects on the broader market structure.'' [20] The Commission expected the Exchange to monitor the scope and operation of the Program and study the data produced during that time with respect to such issues.[21]

In the Notice, the Exchange states that it believes that it has achieved its goal of attracting retail order flow to the Exchange.[22] The Exchange further states that its analysis of the data collected demonstrates that ''there has been consistent retail investor interest in the Program, which has provided tangible price improvement to those retail investors through a competitive pricing process over the course of the pilot.'' [23] The Exchange also concluded that the data shows that the Program ''had an overall negligible impact on broader market quality outside of the Program.'' [24]

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [25] to determine whether the proposal should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposal. Institution of disapproval proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described in greater detail below, the Commission seeks and encourages interested persons to provide additional comment on the proposal.

Pursuant to Section 19(b)(2)(B) of the Act,[26] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act,[27] which requires that the rules of an exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and which prohibits the rules of an exchange from being designed to permit unfair discrimination between customers, issuers, brokers, or dealers, and with Section 6(b)(8) of the Act, which requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[28]

The Program was intended to create additional price improvement opportunities for retail investors by segmenting retail order flow on the Exchange.[29] When the Commission initially approved the Program on a pilot basis, it explained that it would monitor the Program throughout the pilot period for its potential effects on public price discovery and on the broader market structure.[30] The Commission expressed its view that the Program should not cause a major shift in market structure, but instead, it would closely replicate the trading dynamics that exist in the over-the-counter markets to present another competitive venue for retail order flow execution.[31] As explained above, the Exchange provides an analysis of what it considers to be the economic benefits for retail investors and the marketplace flowing from operation of the Program.[32] The Exchange also concludes, among other things, that the relatively modest volume in the Program limits the potential impact of the Program on the broader market quality on the Exchange, and that Program has not had any significant impact on broader market quality.[33]

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . .

[12] *See* Notice, *supra* note 3 at 41130.

[13] *See id.*

[14] *See id.*

[15] *See id.*

[16] *See id.* at 41130–31.

[17] *See id.* at 41131.

[18] *See* Notice, *supra* note 3.

[19] *See* RPI Order, *supra* note 7, at 71657.

[20] *Id.*

[21] *Id.*

[22] *See* Notice, *supra* note 3, at 41131.

[23] *Id.*

[24] *Id.*

[25] 15 U.S.C. 78s(b)(2)(B).

[26] *Id.*

[27] 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78f(b)(8).

[29] See RPI Approval Order, *supra* note 13, at 71655

[30] *See id.*

[31] *See id.* at 71656.

[32] *See supra* notes 20—22, and Notice, *supra* note 3, at 41131–38.

[33] *See id.* at 413332; 41337.

is on the [SRO] that proposed the rule change.'' [34] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[35] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[36] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change would not be sufficient to justify Commission approval of a proposed rule change.[37]

The Commission questions whether the information and analysis provided by the Exchange support the Exchange's conclusions that the Program has achieved its goals, including whether the Program has not had a significant impact on broader market quality. The Commission seeks additional information and analysis concerning the Program's impact on the broader market; for example, additional information to support the view that the Program has not had a material adverse impact on market quality. The Commission believes it is appropriate to institute proceedings to allow for additional consideration and comment on the issues raised herein, any potential response to comments or supplemental information provided by the Exchange, and any additional independent analysis by the Commission. The Commission believes that these issues raise questions as to whether the Exchange has met its burden to demonstrate, based on the data and analysis provided, that permanent approval of the Program is consistent with the Act, and specifically, with its requirements that the Program be designed to perfect the mechanism of a free and open market and the national market system, protect investors and the public interest, and not be unfairly discriminatory; or not impose an unnecessary or inappropriate burden on competition.[38]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Sections 6(b)(5) and 6(b)(8), or any other provision of the Exchange Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[39]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by December 12, 2018. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by December 26, 2018.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBYX–2018–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBYX–2018–014. The file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–CboeBYX–2018–014 and should be submitted on or before December 12, 2018. Rebuttal comments should be submitted by December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–25341 Filed 11–20–18; 8:45 am]

BILLING CODE 8011–01–P

[34] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[35] *See id.*

[36] *See id.*

[37] *See Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 446–47 (D.C. Cir. 2017) (rejecting the Commission's reliance on an SRO's own determinations without sufficient evidence of the basis for such determinations).

[38] *See* 15 U.S.C. 78f(b)(4), (5), and (8).

[39] Section 19(b)(2) of the Exchange Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[40] 17 CFR 200.30–3(a)(57) and (58).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Daniel Upham, Chief, Microenterprise

Development Division, Office of Capital Access, Small Business Administration, 409 3rd Street, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Daniel Upham, Chief, Microenterprise Development Division, Office of Capital Access, *Daniel.upham@sba.gov* 202–205–7001, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov*.

SUPPLEMENTARY INFORMATION: Information collection is needed to ensure that Microloan Program activity meets the statutory goals of assisting mandated target market. The information is used by the reporting participants and the SBA to assist with portfolio management, risk management, loan servicing, oversight and compliance, data management and understanding of short and long term trends and development of outcome measures.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: Microloan Program Electronic Reporting System (MPERS) (MPERsystem).

Description of Respondents: SBA reporting participants in the Microloan Program.

Form Number: N/A.

Total Estimated Annual Responses: 170.

Total Estimated Annual Hour Burden: 3,080.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25335 Filed 11–20–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Cynthia Pitts, Director, Office of Disaster Assistance, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Cynthia Pitts, Director, Office of Disaster Assistance, *Cynthia.pitts@sba.gov* 202–205–7570, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov*.

SUPPLEMENTARY INFORMATION: Prior to Small Business Administration (SBA) approval of subsequent loan disbursement, disaster loan borrowers are required to submit information to demonstrate that they used loan proceeds for authorized purposes only and to make certain certification regarding current financial condition and previously reported compensation paid in connection with the loan.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: Borrower's Progress Certification.

Description of Respondents: Disaster loan Borrowers.

Form Number: SBA Form 1366.

Total Estimated Annual Responses: 14,218.

Total Estimated Annual Hour Burden: 7,106.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25348 Filed 11–20–18; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before January 22, 2019.

ADDRESSES: Send all comments to Cynthia Pitts, Director, Office of Disaster Assistance, Small Business Administration, 409 3rd Street, 6th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Cynthia Pitts, Director, Office of Disaster Assistance, *Cynthia.pitts@sba.gov* 202–205–7570, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov*.

SUPPLEMENTARY INFORMATION: A team of Quality Assurance staff at the Disaster Assistance Center (DASC) will conduct a brief telephone survey of customers to determine their satisfaction with the services received from the (DASC) and the Field Operations Centers. The result will help the Agency to improve where necessary, the delivery of critical financial assistance to disaster victims.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: Disaster Assistance Customer Satisfaction Survey.

Description of Respondents: Disaster Customers satisfaction with service received.

Form Number: SBA Form 2313FOC, 2313CSC.

Total Estimated Annual Responses: 2,400.

Total Estimated Annual Hour Burden: 199.

Curtis Rich,

Management Analyst.

[FR Doc. 2018–25357 Filed 11–20–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 10595]

60-Day Notice of Proposed Information Collection: Overseas Schools Grant Status Report

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to January 22, 2019.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Docket Number: DOS–2018–0051'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: shearertp@state.gov*.
- *Regular Mail:* Send written comments to: Office of Overseas Schools, U.S. Department of State, 2201 C Street NW, Washington, DC 20520.
- *Fax:* 202–261–8224.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Thomas Shearer, Department of State, Office of Overseas Schools, A/OPR/OS, Room H328, SA–1, Washington, DC 20522–0132, who may be reached on 202–261–8200 or at *shearertp@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Overseas Schools Grant Status Report.
- *OMB Control Number:* 1405–0033.
- *Type of Request:* Extension of a currently approved collection.
- *Originating Office:* Bureau of Administration, A/OPR/OS.
- *Form Number:* DS–2028.
- *Respondents:* Overseas schools grantees.
- *Estimated Number of Respondents:* 192.
- *Estimated Number of Responses:* 192.
- *Average Time per Response:* 15 minutes.
- *Total Estimated Burden Time:* 48 hours.
- *Frequency:* Annually.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Office of Overseas Schools of the Department of State (A/OPR/OS) is responsible for determining that adequate educational opportunities exist at Foreign Service Posts for dependents of U.S. Government personnel stationed abroad, and for assisting American-sponsored overseas schools to demonstrate U.S. educational philosophy and practice. The information gathered provides the technical and professional staff of A/OPR/OS the means by which obligations, expenditures and reimbursements of the grant funds are monitored to ensure the grantee is in compliance with the terms of the grant.

Methodology

Information is collected via electronic and paper submission.

Seth M. Rogier,

Acting Executive Director, Bureau of Administration, Department of State.

[FR Doc. 2018–25365 Filed 11–20–18; 8:45 am]

BILLING CODE 4710–24–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36245]

Paul Didelius—Continuance in Control Exemption—KET, LLC

Paul Didelius (Didelius), an individual and noncarrier,[1] has filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of KET, LLC (KET), upon KET's becoming a Class III rail carrier.

This transaction is related to a concurrently filed verified notice of exemption in *KET, LLC—Operation Exemption—Lines of Railroad in Benton County, Wash.,* Docket No. FD 36244, in which KET seeks Board approval under 49 CFR 1150.31 to operate two industrial spurs totaling approximately 1.28 miles in length in Kennewick and Hedges, Benton County, Wash.

The transaction may be consummated on or after December 5, 2018, the effective date of the exemption (30 days after the verified notice of exemption was filed).

Didelius represents that: (1) The rail properties that will be operated and controlled by Didelius, namely LRY, YCR, CCET, WRL, CWW, and KET, do not physically connect; (2) there are no plans to acquire additional rail lines for the purpose of making a connection; and (3) each of the carriers involved in the continuance in control transaction is a Class III carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption

[1] Didelius currently owns 100% of LRY, LLC d/b/a Lake Railway (LRY), a Class III carrier that leases and operates rail lines owned by Union Pacific Railroad Company and Lake County, Or., in California and Oregon; 49% of YCR Corporation (YCR), a Class III rail carrier established for the purpose of leasing and operating a line of railroad owned by Yakima County, Wash.; 100% of CCET, LLC (CCET), a Class III short line rail carrier organized for the purpose of leasing and operating a rail line owned by Norfolk Southern Railway Company in Ohio; 100% of WRL, LLC (WRL), a Class III carrier that leases and operates a rail line owned by Port of Royal Slope, a Washington state municipal corporation, in Washington; and 100% of CWW, LLC (CWW), a Class III carrier that leases and operates a line of railroad owned by the Port of Columbia, Wash.

is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 28, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36245, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on James H.M. Savage, 22 Rockingham Court, Germantown, MD 20874.

Board decisions and notices are available on our website at *www.stb.gov*.

Decided: November 16, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–25413 Filed 11–20–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36220]

CSX Transportation, Inc.—Lease—Western and Atlantic Railroad

AGENCY: Surface Transportation Board.

ACTION: Decision No. 1 in FD 36220; Notice of Acceptance of Application; Issuance of Procedural Schedule.

SUMMARY: This decision accepts for consideration the application by CSX Transportation, Inc. to continue to lease approximately 137.33 miles of rail line of the Western and Atlantic Railroad from the State of Georgia. The Board determines that this is a minor transaction as defined by the Board's regulations and adopts a procedural schedule.

DATES: The effective date of this decision is November 21, 2018. Any person who wishes to participate in this proceeding as a party of record (POR) must file a notice of intent to participate no later than December 5, 2018. All comments, protests, requests for conditions, and any other evidence and argument in opposition to the application, including filings by the U.S. Department of Justice (DOJ) and the U.S. Department of Transportation (DOT), must be filed by January 4, 2019. Responses to comments, protests, requests for conditions, and other opposition on the transportation merits of the Lease, and rebuttal in support of the application must be filed by February 1, 2019.

The Board expects to issue its final decision by April 19, 2019, and to make the decision effective by May 19, 2019. For further information respecting dates, see the procedural schedule below.

ADDRESSES: Any filing submitted on the transportation merits in this proceeding must be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions found on the Board's website at *www.stb.gov* at the ''E–FILING'' link. Any person submitting a filing in the traditional paper format should send an original and 10 paper copies of the filing (and also an electronic version) to: Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each filing in this proceeding must be sent (and may be sent by email only if service by email is acceptable to the recipient) to each of the following: (1) U.S. Secretary of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590; (2) Attorney General of the United States, c/o Assistant Attorney General, Antitrust Division, Room 3109, Department of Justice, Washington, DC 20530; (3) Louis E. Gitomer (representing CSXT), Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204; and (4) any other person designated as a POR on the service list notice (as explained below, the service list notice will be issued as soon after December 5, 2018, as practicable).

FOR FURTHER INFORMATION CONTACT: Lisa Novins, (202) 245–0389. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Surface Transportation Board (Board) is accepting for consideration the application submitted on October 22, 2018, by CSX Transportation, Inc. (CSXT). CSXT seeks Board approval under 49 U.S.C. 11323 to continue to lease from the State of Georgia (Georgia) approximately 137.33 miles of rail line of the Western and Atlantic Railroad (W&A), a non-operating carrier owned by Georgia, acting by and through the State Properties Commission, between milepost 0 at Central Avenue in the City of Atlanta, Ga., and milepost 137.28 at the centerline of Interstate 24 in the City of Chattanooga, Tenn. (the Line). On November 2, 2018, Georgia, acting by and through the State Properties Commission, filed a letter in support of CSXT's application.

The Board finds that the proposed transaction (the Lease) is a ''minor transaction'' under 49 CFR 1180.2(c) and that the application is complete. The Board adopts a procedural schedule for consideration of the application, under which the Board's final decision would be expected to be issued by April 19, 2019, and would become effective by May 19, 2019.

As a condition to the Lease, CSXT states that it has agreed to seek authority to abandon two lines that are not part of the Line in order to allow Georgia to expand its Silver Comet recreational trail: (1) A 2.32-mile long railroad line between milepost S.G. 579.29 and milepost S.G. 581.61 in Cobb County, Ga., *see CSX Transportation, Inc.—Abandonment Exemption—in Cobb County, Ga.,* AB 55 (Sub-No. 784X); and (2) a 4.3-mile line between milepost S.G. 579.29 and milepost 575.00 in Cobb County, Ga. (Appl. 18.)

CSXT is a Class I railroad and W&A is a non-operating Class III railroad that is owned by Georgia, acting by and through the State Properties Commission. (Appl. 3, 5.) According to CSXT, it and its predecessors have been the only railroads operating the Line since 1890. (*Id.* at 4.) CSXT states that it provides overhead and local service over the Line, that the Norfolk Southern Railway Company (NSR) intersects with the Line in Chattanooga, Tenn., and Dalton, Ga.,[1] and that CSXT interchanges traffic in Elizabeth, Ga., with the Georgia Northeastern Railroad Company, Inc. (GNRR). (*Id.*) CSXT states that the current lease expires on December 31, 2019, and that the new lease for the Line is for an additional 50 years. (*Id.* at 14, 17.) CSXT further states that it will retain responsibility for dispatching, track maintenance, capital improvements, and serving shippers under the Lease. (*Id.* at 14.)

Discontinuances/Abandonments. CSXT states that it does not anticipate discontinuing service over or abandoning the Line or any portion of the Line. (Appl. 18.) However, CSXT has agreed to seek authority to abandon two of its lines that are not part of the Line to allow Georgia to expand its Silver Comet recreational trail, which is a material condition of the Lease. (Appl. 18, citing *id.* at Ex. 2, Lease, section 11.03.) On October 15, 2018, CSXT filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon the 2.32-mile line between milepost S.G. 579.29 and milepost S.G. 581.61 in Cobb County, Ga. in Docket No. AB 55 (Sub-

[1] CSXT does not indicate whether it interchanges traffic with NSR at these locations.

No. 784X), *CSX Transportation, Inc.—Abandonment Exemption—in Cobb County, Ga.* Notice of the exemption was served and published in the **Federal Register** on November 2, 2018 (83 FR 55,232). The exemption is scheduled to become effective on December 2, 2018. CSXT states that, if the abandonment is granted, CSXT intends to enter into a trail use agreement with Georgia under the National Trails System Act, 16 U.S.C. 1247(d). (Appl. 18.) With respect to the second line,[2] CSXT states that, in the Lease, CSXT has granted Georgia or its Department of Transportation a first right of refusal to acquire the 4.3-mile line between milepost S.G. 579.29 and milepost 575.00 in Cobb County, Ga. According to CSXT, that line must be acquired within three years of CSXT obtaining abandonment authority. (*Id.*)

Financial Arrangements. According to CSXT, no new securities will be issued in connection with the Lease. (Appl. 8.) CSXT states that, under the Lease, CSXT would pay Georgia a monthly rental of $1,008,333.33, which would increase annually by 2.5% compounded. Additionally, CSXT states that, by July 31 of each year, it would pay Georgia additional rent consisting of 50% of the revenue generated from all agreements, subleases, easements, or licenses attributable to the Line for the previous year. CSXT states that it will not incur any fixed charges as a result of the Lease. (*Id.* at 10.)

Public Interest Considerations. CSXT states that it expects the transaction to be competitively neutral and that it will not result in any lessening of competition, creation of a monopoly, or restraint of trade in freight surface transportation in any region of the United States. (Appl. 9.) In support, CSXT states that competition with NSR between Atlanta and Chattanooga will be maintained at the current level and that the Lease will not impact motor carriers operating between Atlanta and Chattanooga on Interstate 75 or intermodal competition at intermediate points. (*Id.*) CSXT further states that the number of rail carriers serving each shipper on the Line will remain the same and that no shipper now being served by two railroads would have its service limited to one railroad. (*Id.*)

According to CSXT, the Lease will maintain the status quo of the transportation services to rail customers now served by CSXT, as CSXT will continue to serve shippers as it does today. (Appl. 10.) CSXT states that it will continue to provide essential transportation services as it and its predecessors have done since 1890, and that essential services provided by other carriers will not be affected by the Lease. (*Id.* at 8, 10.)

CSXT states that, under the Lease, Georgia has reserved rights that may require the relocation of track, but CSXT is confident that its ability to provide adequate transportation service is protected by the terms of the Lease, which states that any track relocation will not ''unreasonably interfere with the use by [CSXT] of the Leased Property, or unreasonably reduce [CSXT's] operating capacity.'' (Appl. 10, citing *id.* at Ex. 2, Lease, section 1.04(c).) Additionally, CSXT states that Georgia has reserved the right to institute passenger rail service over the Line ''subject to the mutual agreement of [Georgia] and [CSXT] with respect to the impact any such passenger rail may have upon the safety and capacity of, compensation for, and liability in connection with the [Line].'' (*Id.* at 11, citing *id.* at Ex. 2, Lease, section 11.01.)

Time Schedule for Consummation. CSXT states that, pursuant to the Lease, the transaction is scheduled to be consummated January 1, 2020. (Appl. 8.)

Environmental Impacts. CSXT states that the Lease does not require environmental documentation and review under 49 CFR 1105.6(c) because the Lease will not result in CSXT's operations over the Line exceeding the thresholds in 49 CFR 1105.7(e)(4) and (5). (Appl. 15–16.)

Historic Preservation Impacts. CSXT states that the Lease does not require an historic report under 49 CFR 1105.8(b) because the Lease ''is for the purpose of continued rail operations where further [Board] approval is required to abandon any service and there are no plans to dispose of or alter properties subject to [Board] jurisdiction that are 50 years or older.'' (Appl. 17.) CSXT states that it will continue to operate the Line that it has operated for over 120 years. (Appl. 17.)

Labor Impacts. CSXT states that there will be no impact on its employees or on the employees of W&A, because CSXT does not plan to change operations on the Line. Further, CSXT states that there are no W&A employees on the Line. CSXT requests that the Board impose the labor protective conditions set forth in *Mendocino Coast Railway, Inc.—Lease and Operate—California Western Railroad,* 360 I.C.C. 653 (1980), as clarified in *Wilmington Terminal Railroad, Inc.—Purchase and Lease—CSX Transportation, Inc.,* 6 I.C.C.2d 799, 814–826 (1990). (Appl. 11.)

Application Accepted. A transaction that does not involve the control or merger of two or more Class I railroads is not of regional or national transportation significance, and therefore is classified as ''minor'' if: (1) The transaction would clearly not have anticompetitive effects, or (2) any anticompetitive effects would clearly be outweighed by the transaction's contribution to the public interest in meeting significant transportation needs. A transaction not involving the control or merger of two or more Class I railroads is ''significant'' if neither of these determinations can be clearly made. *See* 49 CFR 1180.2(b), (c).

Based on a review of the application, the Board finds that the proposed Lease would be a ''minor transaction'' under 49 CFR 1180.2(c). Nothing in the record thus far suggests that the Lease would have anticompetitive effects, because the Lease proposes to generally maintain the status quo by allowing CSXT to continue operating over the Line as it and its predecessors have done since 1890. The application indicates that, not only would CSXT continue to operate over the Line, but NSR and GNRR would ''retain their existing rights.'' (Appl. 6.) It does not appear, under the terms of the proposed Lease, that any shipper would have fewer competitive rail alternatives as a result of the transaction.

The Board's finding regarding competitive impact is preliminary. The Board will give careful consideration to any claims that any potential anticompetitive effects of the Lease would not be outweighed by its potential benefits.

The Board accepts the application for consideration because it is in substantial compliance with the applicable regulations governing ''minor transactions.'' *See* 49 CFR 1180; 49 U.S.C. 11321–26. The Board reserves the right to require the filing of supplemental information as necessary to complete the record.

Procedural Schedule. Any person who wishes to participate in this proceeding as a POR must file a notice of intent to participate no later than December 5, 2018; requests for discovery from CSXT are due by December 5, 2018; CSXT's discovery responses are due by December 19, 2018; all comments, protests, requests for conditions, and any other evidence and argument in opposition to the application, including filings by DOJ and DOT, must be filed by January 4, 2019; and responses to comments, protests, requests for conditions, and

[2] As of the decided date of this decision, CSXT has not filed for abandonment authority for this line.

other opposition on the transportation merits of the Lease, as well as CSXT's rebuttal in support of the application, must be filed by February 1, 2019. The Board reserves the right to adjust the schedule as circumstances may warrant. For further information regarding dates, see the procedural schedule below.

Notice of Intent To Participate. Any person who wishes to participate in this proceeding as a POR must file with the Board, no later than December 5, 2018, a notice of intent to participate, accompanied by a certificate of service indicating that the notice has been properly served on the U.S. Secretary of Transportation, the Attorney General of the United States, and Mr. Gitomer (representing CSXT), as described above.

If a request is made in the notice of intent to participate to have more than one name added to the service list as a POR representing a particular entity, the extra name will be added to the service list as a ''non-party.'' The list will reflect the Board's policy of allowing only one official representative per party to be placed on the service list, as specified in Press Release No. 97–68 dated August 18, 1997, announcing the implementation of the Board's ''One Party-One Representative'' policy for service lists. Any person designated as a non-party will receive copies of Board decisions, orders, and notices but not copies of official filings. Persons seeking to change their status must accompany that request with a written certification that he or she has complied with the service requirements set forth at 49 CFR 1180.4, and any other requirements set forth in this decision.

Service List Notice. The Board will serve, as soon after December 5, 2018, as practicable, a notice containing the official service list (the service list notice). Each POR will be required to serve upon all other PORs, within 10 days of the service date of the service list notices, copies of all filings previously submitted by that party (to the extent such filings have not previously been served upon such other parties). Each POR will also be required to file with the Board, within 10 days of the service date of the service list notice, a certificate of service indicating that the service required by the preceding sentence has been accomplished. Every filing made by a POR must have its own certificate of service indicating that all PORs on the service list have been served with a copy of the filing. Members of the United States Congress (MOCs) and Governors (GOVs) are not parties of record and need not be served with copies of filings, unless any MOC or GOV has requested to be, and is designated, as a POR.

Service of Decisions, Order, and Notices. The Board will serve copies of its decisions, orders, and notices on those persons who are designated on the official service list as either POR, MOC, GOV, or non-party. All other interested persons are encouraged to secure copies of decisions, orders, and notices via the Board's website at *www.stb.gov* under ''E–LIBRARY/Decisions & Notices.''

Access to Filings. Under the Board's rules, any document filed with the Board (including applications, pleadings, etc.) shall be promptly furnished to interested persons on request, unless subject to a protective order. 49 CFR 1180.4(a)(3). The application and other filings in this proceeding are available on the Board's website at *www.stb.gov* under ''E–LIBRARY/Filings.'' In addition, the application may be obtained from Mr. Gitomer at the address indicated above.

PROCEDURAL SCHEDULE

October 22, 2018	Application filed.
December 5, 2018	Notices of intent to participate in this proceeding due.
	Discovery requests due to CSXT.
December 19, 2018	CSXT's responses to discovery requests due.
January 4, 2019	Comments due from all parties, including the U.S. Secretary of Transportation and the Attorney General, on the transportation merits of the Lease.
February 1, 2019	Responses to comments on the transportation merits of the Lease due.
	CSXT's rebuttal in support of the application due.
March 6, 2019	Close of record on the transportation merits.
April 19, 2019	Date by which a final decision will be served.
May 19, 2019	Date by which a final decision will become effective.

It is ordered:

1. The application in FD 36220 is accepted for consideration.

2. The parties to this proceeding must comply with the procedural schedule adopted by the Board in this proceeding as shown in the procedural schedule above and must comply with the procedural requirements described in this decision.

3. This decision is effective on its service date.

Decided: November 16, 2018.

By the Board, Board Members Begeman and Miller.

Aretha Laws-Byrum,

Clearance Clerk.

[FR Doc. 2018–25388 Filed 11–20–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36244]

KET, LLC—Operation Exemption—Lines of Railroad in Benton County, Wash.

KET, LLC (KET), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate two industrial spurs[1] totaling approximately 1.28 miles of track in Kennewick and Hedges, Benton County, Wash.:

(1) The Kennewick track includes the following: A main industrial spur in the City of Kennewick originating at the connection with the Union Pacific Railroad Company (UP) ''City Lead'' (connecting at its west end to UP's Kalan Industrial Lead) from the east edge of Washington St., running along the line of Bruneau Ave. extending in an easterly direction and terminating east of the intersection of Bruneau Ave. and Kingwood St. This main industrial rail spur also connects with BNSF Railway Company (BNSF) along Bruneau Ave. west of the intersection with N Elm St. The main industrial rail spur is 3,694 feet (approximately 0.7 miles) in length. A branch spur (Ash Grove Spur) diverges from the main industrial rail spur along the line extending east on Bruneau Ave., east of its intersection with N. Gum St. and proceeding in a northeasterly direction, terminating on the property of the Ash Grove Cement Co. at 633 N Ivy Street in Kennewick. The branch spur is 1,476 feet (approximately 0.28 miles) in length.

[1] KET states that it acquired the industrial spurs from the Port of Kennewick, Washington on July 23, 2013. According to KET, the industrial spurs will have no mileposts.

The total length of the Kennewick track is 5,170 feet (0.98 miles).

(2) The Hedges track originates at the connection with UP and runs southeast to the property line of Nutrien Chemical Company, a distance of approximately 1,600 feet (0.30 miles).

This transaction is related to a concurrently filed verified notice of exemption in *Paul Didelius—Continuance in Control Exemption—KET, LLC,* Docket No. FD 36245, in which Paul Didelius seeks Board approval to continue in control of KET under 49 CFR 1180.2(d)(2) upon KET's becoming a Class III rail carrier.

KET certifies that the projected annual revenues as a result of this transaction will remain less than $5 million dollars annually. KET states that no interchange commitments are contemplated for this transaction.

The transaction may be consummated on or after December 5, 2018, the effective date of the exemption (30 days after the verified notice of exemption was filed). If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 CFR 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed by November 28, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings referring to Docket No. FD 36244 must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on applicant's representative, James H.M. Savage, 22 Rockingham Court, Germantown, MD 20874.

According to KET, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our website at *www.stb.gov*.

Decided: November 16, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–25418 Filed 11–20–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Pilot Certification and Qualification Requirements for Air Carrier Operations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on July 31, 2018. The collection involves FAA review of Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements. It also involves FAA review of an institution of higher education's application for the authority to certify its graduates meet the minimum regulatory requirements.

DATES: Written comments should be submitted by December 21, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Barbara Hall at (940) 594–5913, or by email at: *Barbara.L.Hall@faa.gov*.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0755.

Title: Pilot Certification and Qualification Requirements for Air Carrier Operations.

Form Numbers: 8700–1.

Type of Review: This is a renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on July 31, 2018 (83 FR 37039). FAA aviation safety inspectors review the Airline Transport Pilot (ATP) Certification Training Program (CTP) submittals to determine that the program complies with the applicable requirements of 14 CFR 61.156. The programs that comply with the minimum requirements receive approval to begin offering the course to applicants for an ATP certificate with a multiengine class rating or an ATP certificate obtained concurrently with an airplane type rating. FAA aviation inspectors also review an institution of higher education's application for the authority to certify its graduates meet the minimum requirements of 14 CFR 61.160. The institutions of higher education that receive a letter of authorization for their degree program(s) are authorized to place a certifying statement on a graduates' transcript indicating he or she is eligible for a restricted privileges ATP certificate.

Respondents: 41.

Frequency: On occasion.

Estimated Average Burden per Response: 3.1 hours.

Estimated Total Annual Burden: 980 hours.

Issued in Washington, DC, on November 15, 2018.

Barbara Hall,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2018–25360 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Certification of Airports

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on July 31, 2018. The collection involves FAA Form 5280–1, Application for Airport Operating Certificate. Every airport that wants to become a certificated airport must complete this form, as well as provide a draft Airport Certification Manual (ACM). In addition, currently certificated airports must maintain their ACM, as well as keep and maintain records related to training, self-inspection, and other requirements.

These records allow the FAA to verify compliance with regulation safety and operational requirements to ensure that the airports meet the minimum safety requirements, which in turn enhances the safety of the flying public.

DATES: Written comments should be submitted by December 21, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Barbara Hall at (940) 594–5913, or by email at: *Barbara.L.Hall@faa.gov*.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0675.

Title: Certification of Airports, 14 CFR part 139.

Form Numbers: FAA Form 5280–1.

T*ype of Review:* Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on July 31, 2018 (83 FR 37042). The statutory authority to issue airport operating certificates to airports serving certain air carriers and to establish minimum safety standards for the operation of those airports is currently found in Title 49, United States Code (U.S.C.) 44706, Airport operation certificates. The FAA uses this authority to issue requirements for the certification and operation of certain airports that service commercial air carriers. These requirements are contained in Title 14, Code of Federal Regulation part 139 (14 CFR part 139), Certification and Operations: Land Airports Serving Certain Air Carriers, as amended. 14 CFR part 139 establishes certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats. Information collection requirements are used by the FAA to determine an airport operator's compliance with part 139 safety and operational requirements, and to assist airport personnel to perform duties required under the regulation.

Operators of certificated airports are required to complete FAA Form 5280—1 and develop, and comply with, a written document, an Airport Certification Manual (ACM), that details how an airport will comply with the requirements of part 139. The ACM shows the means and procedures whereby the airport will be operated in compliance with part 139, plus other instructions and procedures to help personnel concerned with operation of the airport to perform their duties and responsibilities.

When an airport satisfactorily complies with such requirements, the FAA issues to that facility an airport operating certificate (AOC) that permits an airport to serve air carriers. The FAA periodically inspects these airports to ensure continued compliance with part 139 safety requirements, including the maintenance of specified records. Both the application for an AOC and annual compliance inspections require operators of certificated airports to collect and report certain operational information. The AOC remains in effect as long as the need exists and the operator complies with the terms of the AOC and the ACM.

The likely respondents to new information requests are those civilian U.S. airport certificate holders who operate airports that serve scheduled and unscheduled operations of air carrier aircraft with more than 30 passenger seats (approximately 530 airports). These airport operators already hold an AOC and comply with all current information collection requirements.

Operators of certificated airports are permitted to choose the methodology to report information and can design their own recordkeeping system. As airports vary in size, operations and complexities, the FAA has determined this method of information collection allows airport operators greater flexibility and convenience to comply with reporting and recordkeeping requirements. 100% of the information may be submitted electronically.

The FAA has an automated system, the Certification and Compliance Management Information System (CCMIS), which allows FAA airport safety and certification inspectors to enter into a national database airport inspection information. This information is monitored to detect trends and developing safety issues, to allocate inspection resources, and generally, to be more responsive to the needs of regulated airports.

Respondents: Approximately 530 airports.

Frequency: Information collected on occasion.

Estimated Average Burden per Response: 22 hours.

Estimated Total Annual Burden: 95,191 hours.

Issued in Washington, DC, on November 15, 2018.

Barbara Hall,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–25361 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2018–88]

Petition for Exemption; Summary of Petition Received; Delta Air Lines, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's

awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 11, 2018.

ADDRESSES: Send comments identified by docket number FAA–2018–0948 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

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

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Maria G. Delgado, AIR–673, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198, phone 206–231–3178, email *Maria.G.Delgado@faa.gov;* or Alphonso Pendergrass, ARM–200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, phone 202–267–4713, email *Alphonso.Pendergrass@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Des Moines, Washington, on November 15, 2018.

Chris R. Parker,

Acting Manager, Transport Standards Branch.

Petition for Exemption

Docket No.: FAA–2018–0948.

Petitioner: Delta Air Lines, Inc.

Section(s) of 14 CFR Affected: § 121.310(b)(2)(ii).

Description of Relief Sought: Delta is seeking relief from 14 CFR 121.310(b)(2)(ii), which requires passenger emergency exit markings to be manufactured to meet the interior emergency exit marking requirements under which the airplane was type certificated. Specifically, Delta is proposing the use of graphical/symbolic exit signs rather than the conventional, red text-based signs on its Boeing Model 767–400ER series airplanes.

[FR Doc. 2018–25364 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Report of Inspections Required by Airworthiness Directives

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 19, 2018. Airworthiness Directives are regulations issued to require corrective action to resolve an unsafe condition in aircraft, engines, propellers, and appliances. Reports of inspections are often needed when emergency corrective action is taken to determine if the action was adequate to correct the unsafe condition. The respondents are aircraft owners and operators.

DATES: Written comments should be submitted by December 21, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Barbara Hall at (940) 594–5913, or by email at: *Barbara.L.Hall@faa.gov.*

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0056.

Title: Report of Inspections Required by Airworthiness Directives.

Form Numbers: There are no FAA forms associated with this collection.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 19, 2018 (83 FR 47397). Title 14 CFR part 39, Airworthiness Directives (AD), authorized by §§ 40113(a), 44701, and 44702 of Title 49 United States Code, prescribes how the FAA issues ADs.

The FAA issues ADs when an unsafe condition is discovered on a specific aircraft type. Specific information may be required from aircraft owners/operators if an unsafe condition requires more information to develop corrective action. If it is necessary for the aircraft manufacturer or airworthiness authority to evaluate the information, owners/operators will be instructed to send the information to them.

Respondents: Approximately 1,120 aircraft owners/operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: 28,000 hours.

Issued in Washington, DC, on November 15, 2018.

Barbara Hall,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–25359 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

[DOT–OST–2018–0174]

Department of Transportation Advisory Committee on Human Trafficking; Notice of Public Meeting

AGENCY: Office of the Secretary of Transportation, Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting of the Department of Transportation Advisory Committee on Human Trafficking.

DATES: The meeting will be held on December 6, 2018, from 9:30 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Individuals wishing for audio participation and any person requiring accessibility accommodations should contact the Official listed in the next section.

FOR FURTHER INFORMATION CONTACT: David Short, Designated Federal Officer, U.S. Department of Transportation, at *trafficking@dot.gov* or (202) 366–8822. Also visit the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht.*

SUPPLEMENTARY INFORMATION:

I. Background

ACHT was created in accordance with Section 5 of the *Combating Human Trafficking in Commercial Vehicles Act* (Pub. L. 115–99) to make recommendations to the Secretary of Transportation on actions the Department can take to help combat human trafficking, and to develop recommended best practices for States and State and local transportation stakeholders in combatting human trafficking.

II. Agenda

At the December 6, 2018, meeting, the agenda will cover the following topics:

- Welcome and Introductions
- ACHT Overview and Requirements
- DOT's Counter-Trafficking Initiatives
- Public Participation
- Subcommittees, Next Steps, and Timeline

A final agenda will be posted on the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht* at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public on a first-come, first served basis, as space is limited. Members of the public who wish to attend in-person are asked to register, including name and affiliation, to *trafficking@dot.gov* by November 26, 2018. Individuals requesting accessibility accommodations, such as sign language, interpretation, or other ancillary aids, may do so via email at: *trafficking@dot.gov* by November 26, 2018.

There will be 30 minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the Office of the Secretary may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on November 26, 2018, for inclusion in the meeting records and for circulation to ACHT members. Written comments timely submitted from those not selected to speak will nonetheless be accepted and considered as part of the record.

Persons who wish to submit written comments for consideration by ACHT during the meeting must submit them no later than 5:00 p.m. EDT on November 26, 2018, to ensure transmission to ACHT prior to the meeting. Comments received after that date and time will be distributed to the members but may not be reviewed prior to the meeting.

Copies of the meeting minutes will be available on the ACHT internet website at *https://www.transportation.gov/stophumantrafficking/acht.*

* * * * *

Dated: November 15, 2018.

Joel Szabat,

Deputy Assistant Secretary, Aviation and International Affairs.

[FR Doc. 2018–25380 Filed 11–20–18; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On November 15, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals:

1. ABAHUSSAIN, Mansour Othman M. (a.k.a. ABAHUSEYIN, Mansur Othman M; a.k.a. HUSSEIN, Mansour Othman Aba); DOB 11 Aug 1972; alt. DOB 10 Aug 1972; POB Majmaa, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport S059033 (Saudi Arabia) issued 22 Feb 2016 expires 28 Dec 2020 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of Executive Order 13818 (E.O. 13818) of December 20, 2017, ''Blocking the Property of Persons Involved in Serious Human Rights Abuse or Corruption,'' for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

2. ALARIFI, Naif Hassan S. (a.k.a. AL–ARIFI, Nayif Hasan Saad); DOB 28 Feb 1986; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport M644150 (Saudi Arabia) issued 15 Jan 2014 expires 22 Nov 2018 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

3. ALBALAWI, Fahad Shabib A.; DOB 24 Jan 1985; POB Arar, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport N163990 (Saudi Arabia) issued 24 May 2015 expires 30 Mar 2020 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

4. ALBOSTANI, Meshal Saad M. (a.k.a. ALBOST, Meshal Saad M; a.k.a. AL–BOSTANI, Meshal Saad); DOB 27 Mar 1987; nationality Saudi Arabia; Gender Male; Passport R339037 (Saudi Arabia) expires 09 Jun 2020 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

5. ALHARBI, Thaar Ghaleb T.; DOB 01 Aug 1979; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport P723557 (Saudi Arabia) issued 05 Feb 2015 expires 13 Dec 2019 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

6. ALHAWSAWI, Abdulaziz Mohammed M.; DOB 20 Jul 1987; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport P051811 (Saudi Arabia) issued 15 May 2014 expires 23 Mar 2019; National ID No. 1044087474 (Saudi Arabia) (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

7. ALMADANI, Mustafa Mohammed M. (a.k.a. AL–MADANI, Mustafa); DOB 08 Dec 1961; POB Riyadh, Saudi Arabia; alt. POB Makkah, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport P797794 (Saudi Arabia) issued 16 Mar 2015 expires 20 Jan 2020; National ID No. 1011123229 (Saudi Arabia) (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

8. ALOTAIBI, Khalid Aedh G. (a.k.a. ALTAIBI, Khaled Aedh G); DOB 28 Jun 1988; POB Afif, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport P139681 (Saudi Arabia) issued 27 May 2014 expires 04 Apr 2019; National ID No. 1053629885 (Saudi Arabia) (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

9. ALOTAIBI, Badr Lafi M. (a.k.a. AL OTAIBI, Badr Lafi M.); DOB 06 Jul 1973; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport P667604 (Saudi Arabia) issued 07 Jan 2015 expires 13 Nov 2019 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

10. AL–OTAIBI, Mohammad (a.k.a. ALOTAIBI, Mohammed I.); DOB 06 Nov 1964; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

11. ALQAHTANI, Saif Saad Q.; DOB 1973; nationality Saudi Arabia; Gender Male (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

12. ALSEHRI, Waleed Abdullah M. (a.k.a. ALSHEHRI, Waleed Abdullah M.); DOB 05 Nov 1980; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport R120404 (Saudi Arabia) issued 31 May 2015 expires 06 Apr 2020 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

13. ALSEHRI, Turki Muserref M. (a.k.a. ALSEHRI, Turki Musharraf M); DOB 1982; nationality Saudi Arabia; Gender Male (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

14. ALZAHRANI, Mohammed Saad H.; DOB 08 Mar 1988; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport T233763 (Saudi Arabia) issued 16 Jun 2016 expires 23 Apr 2021; National ID No. 1060613203 (Saudi Arabia) (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

15. MUTREB, Maher Abdulaziz M.; DOB 23 May 1971; POB Makkah, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport D088677 (Saudi Arabia) issued 16 Aug 2017 expires 23 Jun 2022 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

16. AL–QAHTANI, Saud (a.k.a. ALQAHTANI, Saud Abdullah S), Riyadh, Saudi Arabia; DOB 07 Jul 1978; POB Riyadh, Saudi Arabia; nationality Saudi Arabia; Gender Male; Passport D079021 (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

17. TUBAIGY, Salah Muhammed A. (a.k.a. AL–TUBAIQI, Salah); DOB 20 Aug 1971; POB Jazan, Saudi Arabia; nationality Saudi Arabia; Gender Male (individual) [GLOMAG].

Designated pursuant to section 1(a)(ii)(A) of E.O. 13818 for being responsible for or complicit in, or having directly or indirectly engaged in, serious human rights abuse.

Dated: November 15, 2018.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–25346 Filed 11–20–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under Federal Advisory Committee Act that the subcommittees of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board (JBL/CS SMRB) will meet from 8:00 a.m. to 5:00 p.m. on the dates indicated below (unless otherwise listed):

Subcommittee	Date	Location
Pulmonary Medicine	November 14, 2018	20 F Conference Center.
Surgery	November 14, 2018	20 F Conference Center.
Oncology-B	November 14, 2018	Phoenix Park Hotel.
Infectious Diseases-B	November 15, 2018	20 F Conference Center.
Oncology-A/D	November 15, 2018	20 F Conference Center.
Hematology	November 16, 2018	20 F Conference Center.
Oncology-C	November 16, 2018	20 F Conference Center.
Cellular & Molecular Medicine	November 19, 2018	20 F Conference Center.
Nephrology	November 27, 2018	20 F Conference Center.
Oncology-E	November 27, 2018	20 F Conference Center.

Subcommittee	Date	Location
Immunology & Dermatology-A	November 28, 2018	20 F Conference Center.
Infectious Diseases-A	November 28, 2018	VA Central Office.*
Mental Health & Behavioral Sciences-B	November 28–29, 2018	20 F Conference Center.
Neurobiology-C	November 28, 2018	20 F Conference Center.
Endocrinology-A	November 29, 2018	20 F Conference Center.
Neurobiology-E	November 30, 2018	20 F Conference Center.
Cardiovascular Studies-A	December 3, 2018	Phoenix Park Hotel.
Endocrinology-B	December 3, 2018	20 F Conference Center.
Neurobiology-B	December 3, 2018	20 F Conference Center.
Mental Health & Behavioral Sciences-A	December 4, 2018	20 F Conference Center.
Special Emphasis Panel on Million Veteran Prog Proj	December 4, 2018	VA Central Office.*
Neurobiology-F	December 5, 2018	VA Central Office.*
Cardiovascular Studies-B	December 6, 2018	20 F Conference Center.
Epidemiology	December 6, 2018	Phoenix Park Hotel.
Gastroenterology	December 6, 2018	20 F Conference Center.
Neurobiology-A	December 7, 2018	20 F Conference Center.
Neurobiology-D	December 7, 2018	20 F Conference Center.
Gulf War Research	December 7, 2018	Phoenix Park Hotel.
Special Panel for Sheep Review	December 11, 2018	VA Central Office.*
Eligibility	January 18, 2018	20 F Conference Center.

The addresses of the meeting sites are: 20 F Conference Center, 20 F Street NW, Washington, DC; Phoenix Park Hotel, 520 North Capital Street NW, Washington, DC; VA Central Office, 1100 First Street NE, Suite 600, Washington, DC.

* Teleconference.

The purpose of the subcommittees is to provide advice on the scientific quality, budget, safety and mission relevance of investigator-initiated research proposals submitted for VA merit review evaluation. Proposals submitted for review include various medical specialties within the general areas of biomedical, behavioral and clinical science research.

These subcommittee meetings will be closed to the public for the review, discussion, and evaluation of initial and renewal research proposals, which involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the subcommittee meetings is in accordance with Title 5 U.S.C. 552b(c)(6) and (9)(B).

Those who would like to obtain a copy of the minutes from the closed subcommittee meetings and rosters of the subcommittee members should contact Holly Krull, Ph.D., Manager, Merit Review Program (10P9B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at (202) 632–8522 or email at *holly.krull@va.gov*.

Dated: November 16, 2018.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–25405 Filed 11–20–18; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 83 Wednesday,
No. 225 November 21, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–FC]

RIN 0938–AT30

Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, we are updating the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by removing the Communication about Pain questions; and retaining two measures that were proposed for removal, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure, in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program beginning with the FY 2021 program year.

DATES:

Effective date: This final rule with comment period is effective on January 1, 2019.

Comment period: To be assured consideration, comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in this final rule with comment period must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on December 3, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1695–FC when commenting on the issues in this final rule with comment period. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1695–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1695–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Control for Unnecessary Increases in Volume of Outpatient Services, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Inpatient Only (IPO) Procedures List, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email

Scott.Talaga@cms.hhs.gov or at 410–786–4142.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov* or at 410–786–1816, Steven Johnson via email *Steven.Johnson@cms.hhs.gov* or at 410–786–3332, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

OPPS New Technology Procedures/Services, contact the New Technology APC email at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Exceptions to the 2 Times Rule, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

OPPS Pass-Through Devices, contact the Device Pass-Through email at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov* or at 410–786–2682.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program measures, contact Nekeshia McInnis via email *Nekeshia.McInnis@cms.hhs.gov*.

Rural Hospital Payments, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Publishing Office. This database can be accessed via the internet at *https://www.gpo.gov/fdsys/*.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

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Table of Contents

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2019. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

In this final rule with comment period, two quality reporting policies that impact inpatient hospitals are updated due to their time sensitivity. In the Hospital IQR Program, we are updating the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey, which are used to assess patients' experiences of care, effective with October 2019 discharges for the FY 2021 payment determination and subsequent years. This policy addresses public health concerns about opioid overprescribing through patient pain management questions that were recommended for removal in the President's Commission on Combating Drug Addiction and the Opioid Crisis report. In addition, we are finalizing that we will not publicly report any data collected from the Communication Abut Pain questions—a modification from what we proposed. We also are retaining two measures that we proposed for removal in the PCHQR Program beginning with the FY 2021 program year, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure. This policy impacts infection measurement and public reporting for PPS-exempt cancer hospitals and was deferred to this rule from the CY 2019 IPPS/LTCH PPS final rule published in August 2018.

2. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for CMS. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[2] Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including, collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers;
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities, as shown in the table below.

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Quality Priority	Meaningful Measure Area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections
	Preventable Healthcare Harm
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals
	End of Life Care According to Preferences
	Patient's Experience of Care
	Patient Reported Functional Outcomes
Promote Effective Communication and Coordination of Care	Medication Management
	Admissions and Readmissions to Hospitals
	Transfer of Health Information and Interoperability
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care
	Management of Chronic Conditions
	Prevention, Treatment, and Management of Mental Health
	Prevention and Treatment of Opioid and Substance Use Disorders
	Risk Adjusted Mortality
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care
	Community Engagement
Make Care Affordable	Appropriate Use of Healthcare
	Patient-Focused Episode of Care
	Risk Adjusted Total Cost of Care

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By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

We received numerous comments from stakeholders regarding the Meaningful Measures Initiative and the impact of its implementation in CMS' quality programs. Many of these comments pertained to specific program proposals, and are discussed in the appropriate program-specific sections of this final rule with comment period. However, commenters also provided insights and recommendations for the ongoing development of the Meaningful Measures Initiative generally, including: ensuring transparency in public reporting and usability of publicly reported data; evaluating the benefit of individual measures to patients via use in quality programs weighed against the burden to providers of collecting and

reporting that measure data; and identifying additional opportunities for alignment across CMS quality programs. We look forward to continuing to work with stakeholders to refine and further implement the Meaningful Measures Initiative, and will take commenters' insights and recommendations into account moving forward.

3. Summary of the Major Provisions

• *OPPS Update:* For CY 2019, we are increasing the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 1.35 percent. This increase factor is based on the final hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 will be approximately $74.1 billion, an increase of approximately $5.8 billion compared to estimated CY 2018 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements, by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

• *Comprehensive APCs:* For CY 2019, we are creating three new comprehensive APCs (C–APCs). These new C–APCs include ears, nose, and throat (ENT) and vascular procedures. This increases the total number of C–APCs to 65.

• *Changes to the Inpatient Only List:* For CY 2019, we are removing four procedures from the inpatient only list and adding one procedure to the list.

• *Method to Control Unnecessary Increases in Volume of Outpatient Services:* To the extent that similar services are safely provided in more than one setting, it is not prudent for the OPPS to pay more for such services because that leads to an unnecessary increase in the number of those services provided in the OPPS setting. We believe that capping the OPPS payment at the Physician Fee Schedule (PFS)-equivalent rate is an effective method to control the volume of the unnecessary increases in certain services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method of capping payment will control unnecessary volume increases both in terms of numbers of covered outpatient department services furnished and costs of those services. Therefore, as we proposed, we are using our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus provider-based department (PBD) of a hospital (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. We will be phasing in the application of the reduction in payment for code G0463 in this setting over 2 years. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service. In other words, these departments will be paid 70 percent of the OPPS rate for the clinic visit service in CY 2019. In CY 2020 and subsequent years, these departments will be paid the site-specific PFS rate for the clinic visit service. That is, these departments will be paid 40 percent of the OPPS rate for the clinic visit in CY 2020 and subsequent years. In addition to this proposal, we solicited public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization. The public comment we received will be considered for future rulemaking.

• *Expansion of Clinical Families of Services at Excepted Off-Campus Provider-Based Departments (PBDs) of a Hospital:* For CY 2019, we proposed that if an excepted off-campus PBD furnished items and services from a clinical family of services from which it did not furnish items and services (and subsequently bill for those items and services) during a baseline period, services from the new clinical family of services would not be covered OPD services. Instead, services in the new clinical family of services would be paid under the PFS. While we are not finalizing this proposal at this time, we intend to monitor the expansion of services in excepted off-campus PBDs.

• *Application of 340B Drug Payment Policy to Nonexcepted Off-Campus Provider-Based Departments of a Hospital:* For CY 2019, as we proposed, we are paying the average sales price (ASP) minus 22.5 percent under the PFS for separately payable 340B-acquired drugs furnished by nonexcepted, off-campus provider-based departments (PBDs) of a hospital. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

• *Payment Policy for Biosimilar Biological Products without Pass-Through Status That Are Acquired under the 340B Program:* For CY 2019, we are making payment for nonpass-through biosimilars acquired under the 340B program at ASP minus 22.5 percent of the biosimilar's own ASP rather than ASP minus 22.5 percent of the reference product's ASP.

• *Payment of Drugs, Biologicals, and Radiopharmaceuticals If Average Sales Price (ASP) Data Are Not Available:* For CY 2019, we are making payment for separately payable drugs and biologicals that do not have pass-through payment status and are not acquired under the 340B Program at wholesale acquisition cost (WAC)+3 percent instead of WAC+6 percent if ASP data are not available. If WAC data are not available for a drug or biological product, we are continuing our policy to pay for separately payable drugs and biologicals at 95 percent of the average wholesale price (AWP). Drugs and biologicals that are acquired under the 340B Program will continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

• *Device-Intensive Procedure Criteria:* For CY 2019, we are modifying the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. We also are allowing procedures with a device offset percentage of greater than 30 percent to qualify as device-intensive procedures.

• *Device Pass-Through Payment Applications:* For CY 2019, we evaluated seven applications for device pass-through payments and based on public comments received, we are approving one of these applications for device pass-through payment status.

• *New Technology APC Payment for Extremely Low-Volume Procedures:* For CY 2019 and future years, we are establishing a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims using our equitable adjustment authority under section 1833(t)(2)(E) of the Act. We will use a ''smoothing methodology'' based on multiple years of claims data to

establish a more stable rate for services assigned to New Technology APCs with fewer than 100 claims per year under the OPPS. Under this policy, we will calculate the geometric mean costs, the median costs, and the arithmetic mean costs for these procedures and adopt through our annual rulemaking the most appropriate payment rate for the service using one of these methodologies. We will use this approach to establish a payment rate for each low-volume service both for purposes of assigning the service to a New Technology APC and to a clinical APC at the conclusion of payment for the service through a New Technology APC. In addition, we are excluding services assigned to New Technology APCs from bundling into C–APC procedures.

• *Cancer Hospital Payment Adjustment:* For CY 2019, we are continuing to provide additional payments to cancer hospitals so that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, we are providing that a target PCR of 0.88 will be used to determine the CY 2019 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *Rural Adjustment:* For 2019 and subsequent years, we are continuing the 7.1 percent adjustment to OPPS payments for certain rural SCHs, including essential access community hospitals (EACHs). We intend to continue the 7.1 percent adjustment for future years in the absence of data to suggest a different percentage adjustment should apply.

• *Ambulatory Surgical Center (ASC) Payment Update:* For CYs 2019 through 2023, we are updating the ASC payment system using the hospital market basket update instead of the CPI–U. However, during this 5-year period, we intend to examine whether such adjustment leads to a migration of services from other settings to the ASC setting. Using the hospital market basket methodology, for CY 2019, we are increasing payment rates under the ASC payment system by 2.1 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 2.9 percent minus a MFP adjustment required by the Affordable Care Act of 0.8 percentage point.

Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 will be approximately $4.85 billion, an increase of approximately $200 million compared to estimated CY 2018 Medicare payments to ASCs. We note that the CY 2019 ASC payment update, under our prior policy, would have been 1.8 percent, based on a projected CPI–U update of 2.6 percent minus a MFP adjustment required by the Affordable Care Act of 0.8 percentage point. In addition, we will continue to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner for future policy development.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2019, we are revising our definition of ''surgery'' in the ASC payment system to account for certain ''surgery-like'' procedures that are assigned codes outside the Current Procedural Terminology (CPT) surgical range. In addition, as we proposed, we are adding 12 cardiac catheterization procedures, and, in response to public comments, an additional 5 related procedures to the ASC covered procedures list. At this time, we are not finalizing our proposal to establish an additional review of recently added procedures to the ASC covered procedures list.

• *Payment for Non-Opioid Pain Management Therapy:* For CY 2019, in response to the recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis, we are changing the packaging policy for certain drugs when administered in the ASC setting and providing separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program, we are making changes effective with this final rule with comment period and for the CY 2019, CY 2020, and CY 2021 payment determinations and subsequent years. Effective on the effective date of this final rule with comment period, we are codifying several previously established policies: to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets at 42 CFR 419.46(h)(1); to use the rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns at 42 CFR 419.46(h)(3); and to immediately remove measures as a result of patient safety concerns at 42 CFR 419.46(h)(2). Effective on the effective date of this final rule with comment period, we also are updating measure removal Factor 7; adding a new removal Factor 8; and codifying our measure removal policies and factors. We also are providing clarification of our criteria for ''topped-out'' measures. These changes align the Hospital OQR Program measure removal factors with those used in the ASCQR Program.

Beginning with CY 2019, we are updating the frequency with which we will release a Hospital OQR Program Specifications Manual, such that it will occur every 12 months—a modification from what we proposed.

For the CY 2020 payment determination and subsequent years, we are updating the participation status requirements by removing the Notice of Participation (NOP) form; extending the reporting period for the OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years; and removing the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel measure.

Beginning with the CY 2021 payment determination and subsequent years, we are removing the following seven measures: OP–5: Median Time to ECG; OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; OP–17: Tracking Clinical Results between Visits; and OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. We are not finalizing our proposals to remove the OP–29 or OP–31 measures.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are making changes in policies effective with this final rule with comment period and for the CY 2019, CY 2020, and CY 2021 payment determinations and subsequent years. Effective on the effective date of this final rule with comment period, we are removing one measure removal factor; adding two new measure removal factors; and updating the regulations to better reflect our measure removal policies. We also are making one clarification to measure removal Factor

1. These changes align the ASCQR Program measure removal factors with those used in the Hospital OQR Program.

Beginning with the CY 2020 payment determination and subsequent years, we are extending the reporting period for the ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure to 3 years; and removing the ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel measure.

Beginning with the CY 2021 payment determination and subsequent years, we are removing the ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use measure. We are not finalizing our proposals to remove the following measures: ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. We also are not finalizing our proposals to remove the following measures: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission, but are retaining these measures in the ASCQR Program and suspending data collection for them until further action in rulemaking with the goal of revising the measures.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In this final rule with comment period, we are finalizing a modification of our proposals to update the HCAHPS Survey measure by finalizing the removal of the Communication About Pain questions from the HCAHPS Survey for the Hospital IQR Program, effective with October 2019 discharges for the FY 2021 payment determination and subsequent years. In addition, instead of publicly reporting the data from October 2020 until October 2022 and then subsequently discontinuing reporting as proposed, we are finalizing that we will not publicly report any data collected from the Communication About Pain questions.

4. Summary of Costs and Benefits

In sections XXI. and XXII. of this CY 2019 OPPS/ASC final rule with comment period, we set forth a detailed analysis of the regulatory and Federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 62 in section XXI. of this final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2019 compared to all estimated OPPS payments in CY 2018. We estimate that the policies in this final rule with comment period will result in a 0.6 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2019, including beneficiary cost-sharing, to the approximately 3,840 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $360 million compared to CY 2018 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 15.1 percent decrease in CY 2019 payments to CMHCs relative to their CY 2018 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2019 IPPS final rule wage indexes will result in no estimated payment change for urban hospitals under the OPPS and an estimated decrease of 0.2 percent for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C. of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2019 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the required reduction to the cancer hospital payment adjustment required by section 16002 of the 21st Century Cures Act for CY 2019, the target payment-to-cost ratio (PCR) for CY 2019 remains the same as in CY 2018 and therefore does not impact the budget neutrality adjustments.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2019 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 1.35 percent and applying that increase factor to the conversion factor for CY 2019. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that rural and urban hospitals will experience an increase of approximately 1.4 percent for urban hospitals and 1.3 percent for rural hospitals. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase of 1.4 percent, minor teaching hospitals will experience an increase of 1.3 percent, and major teaching hospitals will experience an increase of 1.5 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership, hospitals with proprietary ownership, and hospitals with government ownership will all experience an increase of 1.4 percent in payments.

e. Impacts of the Policy To Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this CY 2019 OPPS/ASC final rule with comment period, we discuss our CY 2019 proposal and finalized policies to control for unnecessary increases in the volume of outpatient service by paying for clinic visits furnished at an off-campus PBD of a hospital at a PFS-equivalent rate under the OPPS rather than at the standard OPPS rate. As a result of this finalized policy, we estimated decreases of 0.6 percent to urban hospitals, and estimated decreases of 0.6 percent to rural hospitals, with the estimated effect for individual groups of hospitals depending on the volume of clinic visits provided at the hospitals' off-campus PBDs.

f. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2019 payment rates, compared to estimated CY 2018 payment rates, generally ranges between an increase of 1 and 3 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates will increase payments by $80 million under the ASC payment system in CY 2019,

compared to an increase of $60 million if we had applied an update based on CPI–U.

c. Impact of the Changes to the Hospital OQR Program

Across 3,300 hospitals participating in the Hospital OQR Program, we estimate that our requirements will result in the following changes to costs and burdens related to information collection for the Hospital OQR Program compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 681,735 hours and a total collection of information cost reduction of approximately $24.9 million for the CY 2021 payment determination due to the removal of four measures: OP–5, OP–12, OP–17, and OP–30.

Further, we anticipate that the removal of a total of eight measures will result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures, as well as the tools we need to collect, validate, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

d. Impact of the Changes to the ASCQR Program

Across 3,937 ASCs participating in the ASCQR Program, we estimate that our requirements will result in the following changes to costs and burdens related to information collection for the ASCQR Program, compared to previously adopted requirements: (1) No change in the total collection of information burden or costs for the CY 2020 payment determination; (2) a total collection of information burden reduction of 62,008 hours and a total collection of information cost reduction of approximately $2,268,244 for the CY 2021 payment determination due to the removal of ASC–10.

Further, we anticipate that the removal of ASC–10 will result in a reduction in costs unrelated to information collection. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. Also, when measures are in multiple programs, maintaining the specifications for those measures as well as the tools we need to collect, analyze, and publicly report the measure data may result in costs to CMS. In addition, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Social Security Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of this final rule with comment period. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use (section 1833(t)(2)(B) of the Act). In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to

the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals include:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under the Maryland All-Payer Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106–113, and redesignated by section 202(a)(2) of Pub. L. 106–113, requires that we consult with an external advisory panel of experts to annually review the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;

• Has a Designated Federal Official (DFO); and

• Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2016, for a 2-year period (81 FR 94378).

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 20, 2018. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting and, when necessary, to solicit nominations for Panel membership, to announce new members and to announce any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). Further information on the 2018 summer meeting can be found in the meeting notice titled ''Medicare Program: Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 20–21, 2018'' (83 FR 19785).

In addition, the Panel has established an operational structure that, in part, currently includes the use of three subcommittees to facilitate its required review process. The three current subcommittees include the following:

• APC Groups and Status Indicator Assignments Subcommittee, which advises the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;

• Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and

• Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 20, 2018 meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 20, 2018 Panel meeting, namely CPT codes and a comprehensive APC for autologous hematopoietic stem cell transplantation, OPPS payment for outpatient clinic visits and restrictions to service line expansions, and packaging policies, were discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143) or are included in the sections of this final rule with comment period that are specific to each recommendation. For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *http://facadatabase.gov*.

F. Public Comments Received in Response to the CY 2019 OPPS/ASC Proposed Rule

We received over 2,990 timely pieces of correspondence on the CY 2019 OPPS/ASC proposed rule that appeared in the **Federal Register** on July 31, 2018 (83 FR 37046). We note that we received some public comments that were outside the scope of the CY 2019 OPPS/ASC proposed rule. Out-of-scope public comments are not addressed in this CY 2019 OPPS/ASC final rule with comment period. Summaries of those public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2018 OPPS/ASC Final Rule With Comment Period

We received over 125 timely pieces of correspondence on the CY 2018 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 14, 2017 (82 FR 59216), some of which contained comments on the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments are set forth in the CY 2019 proposed rule and this final rule with comment period under the appropriate subject matter headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37055), for CY 2019, we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2019, and before January 1, 2020 (CY 2019), using the same basic methodology that we described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52367 through 52370), using updated CY 2017 claims data. That is, as we proposed, we recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the APC relative payment weights for CY 2019, we began with approximately 163 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2017, and before January 1, 2018, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 86 million final action claims to develop the proposed CY 2019 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2019 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/Hospital>OutpatientPPS/index.html.

Addendum N to the proposed rule (which is available via the internet on the CMS website) included the proposed list of bypass codes for CY 2019. The proposed list of bypass codes contained codes that were reported on claims for services in CY 2017 and, therefore, included codes that were in effect in CY 2017 and used for billing, but were deleted for CY 2018. We retained these deleted bypass codes on the proposed CY 2019 bypass list because these codes existed in CY 2017 and were covered OPD services in that period, and CY 2017 claims data were used to calculate CY 2019 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2019 were identified by asterisks (*) in the fourth column of Addendum N.

In the CY 2019 OPPS/ASC proposed rule, we did not propose to remove any codes from the CY 2019 bypass list.

We did not receive any public comments on our general proposal to recalibrate the relative payment weights for each APC based on claims and cost report data for HOPD services or on our proposed bypass code process. Therefore, we are adopting as final the proposed ''pseudo'' single claims process and the final CY 2019 bypass list of 169 HCPCS codes, as displayed in Addendum N to this final rule with comment period (which is available via the internet on the CMS website). For this final rule with comment period, for purposes of recalibrating the final APC relative payment weights for CY 2019, we used approximately 91 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2017 and before January 1, 2018. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this CY 2019 OPPS/ASC final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2019, in the CY 2019 OPPS/ASC proposed rule (83 FR 37055), we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2019 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2017 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2016. For the proposed CY 2019 OPPS payment rates, we used the set of claims processed during CY 2017. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2017 (the year of claims data we used to calculate the proposed CY 2019 OPPS payment rates) and found that the National Uniform Billing Committee (NUBC) did not add any new revenue codes to the NUBC 2017 Data Specifications Manual.

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of the proposed rule and this final rule with comment period.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals currently use an imprecise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while CMS recommended using two alternative allocation methods, ''direct assignment'' or ''dollar value,'' as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for the CY 2014 OPPS to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for CT and MRI (78 FR 74847). Further, we finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use ''square feet'' as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide a sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning CY 2018, with the sunset of the transition policy, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228 and 59229), we finalized a policy to extend the transition policy for 1 additional year and continued to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs for the CY 2018 OPPS.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant

reductions in the imaging APC payment rates.

Table 1 below demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 below provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

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TABLE 1.—PERCENTAGE CHANGE IN ESTIMATE COST FOR CT AND MRI APCs WHEN EXCLUDING CLAIMS FROM PROVIDER USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-4.0%
5522	Level 2 Imaging without Contrast	5.6%
5523	Level 3 Imaging without Contrast	4.2%
5524	Level 4 Imaging without Contrast	5.3%
5571	Level 1 Imaging with Contrast	7.8%
5572	Level 2 Imaging with Contrast	8.3%
5573	Level 3 Imaging with Contrast	2.8%
8005	CT and CTA without Contrast Composite	14.1%
8006	CT and CTA with Contrast Composite	11.5%
8007	MRI and MRA without Contrast Composite	6.5%
8008	MRI and MRA with Contrast Composite	6.8%

TABLE 2.—CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0370	0.0512	0.0774	0.1020
Square Feet Only	0.0300	0.0453	0.0682	0.0928
Direct Assign	0.0554	0.0642	0.1003	0.1198
Dollar Value	0.0435	0.0588	0.0866	0.1134
Direct Assign and Dollar Value	0.0438	0.0589	0.0868	0.1133

Our analysis shows that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 17.5 percent to 2,177 providers and the number of valid CT CCRs has increased by 15.1 percent to 2,251 providers. However, as shown in Table 1 above, nearly all imaging APCs would see an increase in payment rates for CY 2019 if claims from providers that report using the ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a cost allocation method of ''square feet'' as shown in Table 2 above.

In response to provider concerns and to provide added flexibility for hospitals to improve their cost allocation methods, for the CY 2019 OPPS, in the CY 2019 OPPS/ASC proposed rule (83 FR 37056), we proposed to extend our transition policy and remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs with the APCs for CT and MRI identified in Table 2 above. We stated in the proposed rule that this proposed extension would mean that CMS would now be providing 6 years for providers to transition from a ''square feet'' cost allocation method to another cost allocation method. We stated in the proposed rule that we do not believe

another extension in CY 2020 will be warranted and expect to determine the imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed.

Comment: Some commenters supported CMS' proposal to extend its transition policy an additional year and determine imaging APC relative payment weights for CY 2020 using cost data from all providers.

Response: We thank the commenters for their support.

Comment: Some commenters recommended that CMS discontinue the use of CT and MRI cost centers for developing CT and MRI CCRs and use a single diagnostic radiology CCR instead. One commenter suggested that CCRs for CT and MRI are inaccurate, too low, and equalize the payment rates for advanced and nonadvanced imaging. This commenter also noted that if CMS were to use CCRs from all cost allocation methods, including ''square feet,'' such a change would impact technical payments under the Medicare Physician Fee Schedule because OPPS payments for imaging services would fall below the technical payments for such services under the Medicare Physician Fee Schedule and would require a reduction as required by section 1848(b)(4) of the Act.

Further, the commenter noted that a significant number of CT and MRI CCRs are close to zero. The commenter suggested that this probably reflects that the costs of the equipment and dedicated space for these services are likely spread across to other departments of hospitals. The commenter also suggested that hospitals have standard accounting practices for high-cost moveable equipment and that it would be burdensome and inconsistent to apply a different standard for costs associated with CT and MRI.

Response: We appreciate the comments regarding the use of standard CT and MRI cost center CCRs. As we stated in prior rulemaking, we recognize the concerns with regard to the application of the CT and MRI standard cost center CCRs and their use in OPPS ratesetting in lieu of the previously used single diagnostic radiology CCR. As compared to the IPPS, there is greater sensitivity to the cost allocation method being used on the cost report forms for these relatively new standard imaging cost centers under the OPPS due to the limited size of the OPPS payment bundles and because the OPPS applies the CCRs at the departmental level for cost estimation purposes. However, we note that since the time we initially established the transition policy in the OPPS, we have made changes toward making the OPPS more of a prospective payment system, including greater packaging and the development of the comprehensive APCs. As we have made changes to package a greater number of items and services with imaging payments under the OPPS, and CT and MRI procedures are not solely based on the CCR applied to each procedure, we believe there is less sensitivity to imaging payments that is attributable to the cost allocation method being used on the cost report forms.

Table 3 and Table 4 below display the largest and smallest CT and MRI CCRs based on the cost allocation method, respectively. Specifically, Tables 3 and 4 display the minimum, 5th percentile, 10th percentile, 90th percentile, 95th percentile, and maximum CCRs based on the cost allocation method. While we note that there are differences in CT and MRI CCR values by the cost allocation method, we also note that the CT CCR distributions and MRI CCR distributions are largely similar across the cost allocation method. As stated in past rulemaking, we also note that our current trimming methodology excludes CCRs that are +/− 3 standard deviations from the geometric mean. While we acknowledge the commenter's concern that a number of CCRs, particular those CT CCRs from hospitals that use a cost allocation method of ''square feet,'' are below 0.0100, we do not believe it would be appropriate to modify our standard trimming methodology because it is not our general policy to judge the accuracy of hospital charging and hospital cost reporting practices for purposes of ratesetting.

TABLE 3.—SELECTED DISTRIBUTION OF CT CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	Minimum	5th Percentile	10th Percentile	90th Percentile	95th Percentile	Maximum
All Providers	0.0036	0.0115	0.0147	0.1010	0.1399	0.4052
Square Feet Only	0.0036	0.0099	0.0121	0.0922	0.1379	0.4052
Direct Assign	0.0055	0.0222	0.0259	0.1223	0.1534	0.2282
Dollar Value	0.0046	0.0180	0.0223	0.1087	0.1458	0.4009
Direct Assign and Dollar Value	0.0046	0.0179	0.0224	0.1087	0.1493	0.4009

TABLE 4.—SELECTED DISTRIBUTION OF MRI CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	Minimum	5th Percentile	10th Percentile	90th Percentile	95th Percentile	Maximum
All Providers	0.0106	0.0292	0.0355	0.1975	0.2653	0.6700
Square Feet Only	0.0106	0.0247	0.0305	0.1822	0.2469	0.6563
Direct Assign	0.0271	0.0456	0.0525	0.2119	0.2904	0.6081
Dollar Value	0.0175	0.0365	0.0446	0.2187	0.2920	0.6700
Direct Assign and Dollar Value	0.0175	0.0365	0.0447	0.2155	0.2916	0.6700

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In addition, as we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the Physician Fee Schedule where the technical component payment for many imaging services is capped at the OPPS payment amount. We will continue to monitor OPPS imaging payments in the future and consider the potential impacts of payment changes to other payment systems.

Over the past several years, we have encouraged hospitals to use more precise cost reporting methods through cost reporting instructions and communication with Medicare contractors regarding the approval of hospitals' request to switch from the square feet statistical allocation method. While we have not seen a substantial decline in the number of hospitals that use the square feet cost allocation method, and we acknowledge that there are costs and challenges with transitioning to a different accounting method for CT and MRI costs, we continue to believe that adopting CT and MRI cost center CCRs fosters more specific cost reporting and improves the data contained in the electronic cost report data files and, therefore, the accuracy of our cost estimation process for the OPPS relative weights. Therefore, for CY 2019, after consideration of the public comments we received, for CY 2019, we are finalizing our proposal to extend our transition policy for 1 additional year and continue to remove claims from providers that use a ''square feet'' cost allocation method to calculate CT and MRI CCRs for the CY 2019 OPPS.

2. Data Development Process and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2019. The Hospital OPPS page on the CMS website on which this final rule is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the final payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2017 claims that were used to calculate the final payment rates for this CY 2019 OPPS/ASC final rule with comment period.

Previously, the OPPS established the scaled relative weights, on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. In the CY 2019 OPPS/ASC proposed rule (83 FR 37057), we proposed to continue to use geometric mean costs to calculate the relative weights on which the CY 2019 OPPS payment rates are based.

Comment: One commenter believed that revenue code 0815 (Allogeneic Stem Cell Acquisition Services) was inadvertently excluded from the packaged revenue code list for use in the OPPS ratesetting. The commenter stated that this would primarily have an impact on APC 5244 (Level 4 Blood Product Exchange and Related Services) which would potentially include those packaged costs. The commenter requested that CMS include revenue code 0815 on the packaged revenue code list in order to be consistent with the C–APC ratesetting approach from prior years.

Response: We thank the commenter for bringing this omission to our attention. As discussed in the CY 2018 OPPS/ASC final rule with comment period (81 FR 79586), beginning in CY 2017, we would include the revenue code for purposes of identifying costs associated with stem cell transplants. We agree that the revenue code was inadvertently not included on the packaged revenue code list and therefore have included it in this final rule with comment period for the CY 2019 OPPS ratesetting.

After consideration of the public comment on the proposed process we received, we are adding revenue code 0815 to the packaged revenue code list and are finalizing our proposed methodology for calculating geometric mean costs for purposes of creating relative payment weights and subsequent APC payment rates for the CY 2019 OPPS. For more information

regarding the stem cell transplants, we refer readers to section II.A.2.b. of this final rule with comment period. We used the methodology described in sections II.A.2.a. through II.A.2.c. of this final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the OPPS payment rates for CY 2019 shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

We note that this is the first year in which claims data containing lines with the modifier ''PN'' are available, which indicate nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC proposed rule (83 FR 37057), we proposed to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years.

Comment: One commenter requested that CMS not finalize the removal of claims with modifier ''PN'' from the CY 2019 OPPS and future ratesetting. The commenter believed that this could result in unfair adjustments against hospital outpatient departments with large off-campus PBD presence and that CMS should perform ratesetting with and without the modifier in CY 2020 and continue to gather stakeholder input until the impact of removing those lines is fully understood.

Response: While we generally attempt to obtain more information from the claims and cost data available to us, we do so to obtain accurate cost information for OPPS services. As discussed in the proposed rule, we do not believe that lines with modifier ''PN'' should be included as part of the OPPS ratesetting process because they are paid under the otherwise applicable payment system, rather than the OPPS (83 FR 37056 and 37057). We note that the impact of removing these modifier ''PN'' lines has only a nominal effect on the APC geometric mean costs due to the relatively low number of claims reported with modifier ''PN''.

After consideration of the public comment we received, we are finalizing the policy of removing lines with the ''PN'' modifier as proposed.

For details of the claims process used in this final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2019 OPPS/ASC final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37057 through 37058), we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, in order to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2019 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We stated in the proposed rule that we continue to believe that this methodology in CY 2019 would result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that, as discussed in section II.A.2.b. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59234 through 59239), we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. In the CY 2019 OPPS/ASC proposed rule (83 FR 37057 through 37058), we proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products would be reflected in the overall costs of the C–APCs (and, as a result, in the payment rates of the C–APCs), we proposed to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)).

We also referred readers to Addendum B to the CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2019 payment rates for blood and blood products (which are identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through

50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

We did not receive any public comments for these proposals. Therefore, we are finalizing our proposals, without modification, to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs and to not make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs for CY 2019.

(b) Pathogen-Reduced Platelets Payment Rate

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70322 through 70323), we reiterated that we calculate payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. Because HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit), was new for CY 2016, there were no claims data available on the charges and costs for this blood product upon which to apply our blood-specific CCR methodology. Therefore, we established an interim payment rate for HCPCS code P9072 based on a crosswalk to existing blood product HCPCS code P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit), which we believed provided the best proxy for the costs of the new blood product. In addition, we stated that once we had claims data for HCPCS code P9072, we would calculate its payment rate using the claims data that should be available for the code beginning in CY 2018, which is our practice for other blood product HCPCS codes for which claims data have been available for 2 years.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59232) that, although our standard practice for new codes involves using claims data to set payment rates once claims data become available, we were concerned that there may have been confusion among the provider community about the services that HCPCS code P9072 described. That is, as early as 2016, there were discussions about changing the descriptor for HCPCS code P9072 to include the phrase ''or rapid bacterial tested'', which is a less costly technology than pathogen reduction. In addition, effective January 2017, the code descriptor for HCPCS code P9072 was changed to describe rapid bacterial testing of platelets and, effective July 1, 2017, the descriptor for the temporary successor code for HCPCS code P9072 (HCPCS code Q9988) was changed again back to the original descriptor for HCPCS code P9072 that was in place for 2016.

Based on the ongoing discussions involving changes to the original HCPCS code P9072 established in CY 2016, we believed that claims from CY 2016 for pathogen reduced platelets may have potentially reflected certain claims for rapid bacterial testing of platelets. Therefore, we decided to continue to crosswalk the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS P9037 for CY 2018 (82 FR 59232), as had been done previously, to determine the payment rate for services described by HCPCS code P9072. In the CY 2019 OPPS/ASC proposed rule (83 FR 37058), for CY 2019, we discussed that we had reviewed the CY 2017 claims data for the two predecessor codes to HCPCS code P9073 (HCPCS codes P9072 and Q9988), along with the claims data for the CY 2017 temporary code for pathogen test for platelets (HCPCS code Q9987), which describes rapid bacterial testing of platelets.

We found that there were over 2,200 claims billed with either HCPCS code P9072 or Q9988. Accordingly, we believe that there are a sufficient number of claims to use to calculate a payment rate for HCPCS code P9073 for CY 2019. We also performed checks to estimate the share of claims that may have been billed for rapid bacterial testing of platelets as compared to the share of claims that may have been billed for pathogen-reduced, pheresis platelets (based on when HCPCS code P9072 was an active procedure code from January 1, 2017 to June 30, 2017). First, we found that the geometric mean cost for pathogen-reduced, pheresis platelets, as reported by HCPCS code Q9988 when billed separately from rapid bacterial testing of platelets, was $453.87, and that over 1,200 claims were billed for services described by HCPCS code Q9988. Next, we found that the geometric mean cost for rapid bacterial testing of platelets, as reported by HCPCS code Q9987 on claims, was $33.44, and there were 59 claims reported for services described by HCPCS code Q9987, of which 3 were separately paid.

These findings imply that almost all of the claims billed for services reported with HCPCS code P9072 were for pathogen-reduced, pheresis platelets. In addition, the geometric mean cost for services described by HCPCS code P9072, which may contain rapid bacterial testing of platelets claims, was $468.11, which is higher than the geometric mean cost for services described by HCPCS code Q9988 of $453.87, which should not have contained claims for rapid bacterial testing of platelets. Because the geometric mean for services described by HCPCS code Q9987 is only $33.44, it would be expected that if a significant share of claims billed for services described by HCPCS code P9072 were for the rapid bacterial testing of platelets, the geometric mean cost for services described by HCPCS code P9072 would be lower than the geometric mean cost for services described by HCPCS code Q9988. Instead, we found that the geometric mean cost for services described by HCPCS code Q9988 is higher than the geometric mean cost for services described by HCPCS code P9072.

Based on our analysis of claims data, we stated in the CY 2019 OPPS/ASC proposed rule that we believed there were sufficient claims available to establish a payment rate for pathogen-reduced pheresis platelets without using a crosswalk. Therefore, we proposed to calculate the payment rate for services described by HCPCS code P9073 in CY 2019 and in subsequent years using claims payment history, which is the standard methodology used by the OPPS for HCPCS and CPT codes with at least 2 years of claims history. We referred readers to Addendum B of the proposed rule for the proposed payment rate for services described by HCPCS code P9073 reportable under the OPPS. Addendum B is available via the internet on the CMS website.

Comment: Several commenters opposed the proposal to use claims history to calculate the payment rate for services described by HCPCS code P9073. Instead, the commenters requested that CMS calculate the payment rate for services described by HCPCS code P9072 based on a crosswalk to existing blood product HCPCS code P9037 through either CY 2019 or CY 2020. The commenters stated that the acquisition cost for pathogen-reduced platelets is over $600, which is substantially higher than the proposed payment rate for services described by HCPCS code P9073 found in Addendum B to the proposed rule

and closer to the payment rate for services described by HCPCS code P9073. Some commenters indicated that the cost for pathogen-reduced platelets is higher than the cost of leukocytes reduced and irradiated platelets, the product covered by HCPCS code P9073, the crosswalked code. Several of the commenters believed the claim costs for pathogen-reduced platelets were lower than actual costs because of coding errors by providers, providers who did not use pathogen-reduced platelets billing the service, and confusion over whether to use the hospital CCR or the blood center CCR to report charges for pathogen-reduced platelets. One commenter also stated that a provider that billed several claims for pathogen-reduced platelets believed that CMS assigned an unusually low CCR to its claims, leading the provider to report lower than actual costs for the service.

Response: We appreciate the concerns of the commenters. Pathogen-reduced platelets (HCPCS code P9073) are a relatively new service. As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37058), there were many changes to the procedure code billed for pathogen-reduced platelets, as well as with the services covered by the procedure codes for pathogen-reduced platelets and the code descriptors. We had concerns that all of these coding changes could lead to billing confusion. The comments we received from providers, stakeholder groups, and the developer of the pathogen-reduced technology support that there indeed may have been confusion about billing that has led to aberrancies in the data we have available for ratesetting.

After consideration of the public comments we received, we are not finalizing our proposal to calculate the payment rate for services described by HCPCS code P9073 in CY 2019 using claims payment history. Instead, for CY 2019 (that is, for one more year), we are establishing the payment rate for services described by HCPCS code P9073 by performing a crosswalk from the payment amount for services described by HCPCS code P9073 to the payment amount for services described by HCPCS P9037. We refer readers to Addendum B to this final rule with comment period for the final payment rate for services described by HCPCS code P9073 reportable under the OPPS. Addendum B is available via the internet on the CMS website.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37059), for CY 2019, we proposed to use the costs derived from CY 2017 claims data to set the proposed CY 2019 payment rates for brachytherapy sources because CY 2017 is the same year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2019 OPPS. We proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the proposed rule. We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2019 payment rates for brachytherapy sources were included in Addendum B to the proposed rule (which is available via the internet on the CMS website) and were identified with status indicator ''U''. For CY 2019, we proposed to continue to assign status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and to use external data (invoice prices) and other relevant information to establish the proposed APC payment rate for HCPCS code C2645. Specifically, we proposed to set the payment rate at $4.69 per mm^2, the same rate that was in effect for CYs 2017 and 2018.

We note that, for CY 2019, we proposed to assign status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available) to HCPCS code C2644 (Brachytherapy cesium-131 chloride) because this code was not reported on CY 2017 claims. Therefore, we were unable to calculate a proposed payment rate based on the general OPPS ratesetting methodology described earlier. Although HCPCS code C2644 became effective July 1, 2014, there are no CY 2017 claims reporting this code. Therefore, we proposed to assign new proposed status indicator ''E2'' to HCPCS code C2644 in the CY 2019 OPPS.

Comment: One commenter expressed concern regarding CMS' policy to establish prospective payment rates for brachytherapy sources using the general OPPS methodology, which uses costs based on claims data to set the relative payment weights for hospital outpatient services. The commenter stated that, as a result of use of these cost data from claims, payments for low-volume brachytherapy sources have fluctuated significantly under the OPPS.

Response: As we stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74161) when we established a prospective payment for brachytherapy sources, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient; however, with the exception of outlier cases, we believe that such a prospective payment is adequate to ensure access to appropriate care. We acknowledge that payment for brachytherapy sources based on geometric mean costs from a small set of claims may be more variable on a year-to-year basis when compared to geometric mean costs for brachytherapy sources from a larger claims set. However, as illustrated in Table 5 below, we believe that payment for currently payable brachytherapy sources has been relatively consistent over the years and that a prospective payment for brachytherapy sources based on geometric mean costs is appropriate and provides hospitals with the greatest incentives for efficiency in furnishing brachytherapy treatment. For CY 2019 OPPS payment rates for the brachytherapy sources listed in Table 5, we refer readers to Addendum B of this final rule with comment period (which is available via the internet on the CMS website).

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TABLE 5.—CY 2015 THROUGH CY 2018 OPPS PAYMENT FOR BRACHYTHERAPY SOURCES

CY 2019 APC	Short Descriptor	CY 2015 OPPS Payment Rate	CY 2016 OPPS Payment Rate	CY 2017 OPPS Payment Rate	CY 2018 OPPS Payment Rate
2616	Brachytx, non-str, Ytrrium-90	$15,582.68	$16,021.70	$16,507.73	$16,717.59
2632	Iodine I-35 sodium iodide	$13.25	$7.14	$29.93	$26.65
2634	Brachytx, non-str, HA, I-25	$85.81	$85.18	$120.52	$117.66
2635	Brachytx, non-str, HA, P-103	$25.81	$35.24	$25.70	$25.94
2636	Brachy linear, non-str P-103	$19.44	$14.24	$18.65	$27.08
2638	Brachytx, stranded, I-25	$42.42	$38.09	$37.97	$34.73
2639	Brachytx, non-stranded, I-25	$37.05	$36.64	$35.70	$34.66
2640	Brachytx, stranded, P-103	$65.50	$68.78	$73.22	$78.72
2641	Brachytx, non-stranded, P-103	$67.93	$66.23	$65.45	$64.27
2642	Brachytx, stranded, C-131	$105.39	$86.59	$87.61	$87.89
2643	Brachytx, non-stranded, C-131	$54.71	$52.18	$59.19	$87.40
2645	Brachytx, non-str, Gold-198	$37.31	$45.54	$135.30	$122.61
2646	Brachytx, non-str, HDRIr-192	$272.38	$294.04	$281.58	$294.59
2647	Brachytx, NS, Non-HDRIr-192	$53.73	$93.11	$33.83	$19.16
2648	Brachytx planar, p-103	N/A	N/A	$4.69	$4.69
2698	Brachytx, stranded, NOS	$42.42	$38.09	$37.97	$34.73
2699	Brachytx, non-stranded, NOS	$19.44	$14.24	$18.65	$19.16

Note: N/A reflects brachytherapy APCs that did not have a payment rate for a payment year because the brachytherapy source did not have an established C-code.

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After consideration of the public comments we received, we are finalizing our proposal to continue to set the payment rates for brachytherapy sources using our established prospective payment methodology. We also are finalizing our proposal to assign status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and to use external data (invoice prices) and other relevant information to establish the APC payment rate for HCPCS code C2645 for CY 2019.

Lastly, because we were unable to calculate a payment rate for HCPCS code C2644 (Brachytherapy cesium-131 chloride) based on the general OPPS ratesetting methodology, we are finalizing our proposal to assign HCPCS code C2644 status indicator ''E2'' (Items and Services for Which Pricing Information and Claims Data Are Not Available) for CY 2019.

The final CY 2019 payment rates for brachytherapy sources are included in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) and are identified with status indicator ''U''.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be

directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2019

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added one additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62.

Under this policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this final rule with comment period (which is available via the internet on the CMS website).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1'', excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2''. Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'' that is reported with a date of service on the same day or 1 day earlier than the date of service associated with services described by HCPCS code G0378;
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are

not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. Therefore, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) does not apply. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if

there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2019, in the CY 2019 OPPS/ASC proposed rule (83 FR 37061), we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We listed the complexity adjustments proposed for ''J1'' and add-on code combinations for CY 2019, along with all of the other proposed complexity adjustments, in Addendum J to the CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to the proposed rule included the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to the proposed rule also contained summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and were proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations were represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that were proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the proposed rule allowed stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: Several commenters requested that CMS alter the C–APC complexity adjustment eligibility criteria to allow additional code combinations to qualify for complexity adjustments. The commenters requested that CMS consider clusters of ''J1'' and add-on codes, rather than only code pairs, and also consider code combinations of ''J1'' codes and devices such as drug-coated balloons and drug-eluting stents. The commenters also requested that CMS eliminate the 25-claim frequency threshold. Another commenter requested that CMS consider patient complexity and procedures assigned to status indicator ''S'' or ''T'' when evaluating procedures for a complexity adjustment. One commenter suggested that procedures initially eligible for a complexity adjustment by meeting the applicable requirements in a year maintain that complexity adjustment for a total period of 3 years, regardless of whether they continue to meet the criteria after the first year.

In terms of payment for complexity adjustments, one commenter requested that CMS promote the qualifying code combination to two APC levels higher than the originating APC rather than to the next higher paying C–APC. Another commenter suggested that CMS pay the geometric mean cost of the highest ranking procedure in the qualifying code combination at 100 percent, and then each secondary procedure at 50 percent of the geometric mean cost of the secondary procedure.

Other commenters also requested an explanation of how the geometric mean costs of the code combinations evaluated for complexity adjustments are calculated, stating that the geometric mean cost of certain code combinations represented in Addendum J were lower than the geometric mean costs of the primary service when the service is billed without an additional ''J1'' or ''J1'' add-on procedure. Commenters also requested that CMS establish complexity adjustments for the specific code combinations listed in Table 6 below.

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TABLE 6.—C–APC COMPLEXITY ADJUSTMENTS REQUESTED BY COMMENTERS

Primary "J1" HCPCS Code	Secondary "J1" or Add-on HCPCS Code	Primary APC Assignment	Requested Complexity Adjusted APC Assignment
22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2)	22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2, each additional interspace (list separately in addition to code for separate procedure)	5115	5116
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method)	20900 (Bone graft, any donor area; minor or small (eg, dowel or button))	5114	5115
28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method)	28285 (Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy))	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	20900 ((Bone graft, any donor area; minor or small (eg, dowel or button))	5114	5115
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	28292 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method)	5114	5115

Primary "J1" HCPCS Code	Secondary "J1" or Add-on HCPCS Code	Primary APC Assignment	Requested Complexity Adjusted APC Assignment
28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint)	38220 (Diagnostic bone marrow; aspiration(s))	5114	5115
31276 (Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed)	31255 (Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior))	5155	N/A
31288 (Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus)	31255 (Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior))	5155	N/A
31296 (Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)	31297 (Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)	5155	N/A
52214 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands)	C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5373	5374
52234 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm))	C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)	5374	5375

Primary "J1" HCPCS Code	Secondary "J1" or Add-on HCPCS Code	Primary APC Assignment	Requested Complexity Adjusted APC Assignment
52235 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; medium bladder tumor(s) (2.0 to 5.0 cm))	C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5374	5375
52240 (Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s))	C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure))	5375	5376

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Response: We appreciate these comments. However, at this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As stated previously (81 FR 79582), we continue to believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC in order to receive payment in the next higher cost C–APC within the clinical family, are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. If a code combination meets these criteria, the combination receives payment at the next higher cost C–APC. Code combinations that do not meet these criteria receive the C–APC payment rate associated with the primary ''J1'' service. A minimum of 25 claims is already very low for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed. The complexity adjustment cost threshold compares the code combinations to the lowest cost-significant procedure assigned to the APC. If the cost of the code combination does not exceed twice the cost of the lowest cost-significant procedure within the APC, no complexity adjustment is made. Lowering or eliminating this threshold could remove so many claims from the accounting for the primary ''J1'' service that the geometric mean costs attributed to the primary procedure could be skewed.

With regard to the specific complexity adjustments requested by commenters listed in Table 6 above, we note that we did not propose that claims with these code combinations would receive complexity adjustments because they did not meet the cost and frequency criteria for the adjustment. Therefore, we do not believe it is appropriate to change the complexity adjustment criteria at this time, and because the suggested code combinations do not meet the existing criteria, we do not believe it is appropriate to establish complexity adjustments for these code combinations at this time.

Regarding the request for a code combination that qualified for a complexity adjustment in a year to continue to qualify for the adjustment for the next 2 years for a total period of 3 years, we note that we evaluate code combinations each year against our complexity adjustment criteria using the latest available data. At this time, we do not believe it is necessary to expand the ability for code combinations to meet the complexity adjustment criteria in this manner because we believe that the existing criteria that were already established sufficiently reflect those combinations of procedures that are commonly billed together and are costly enough to merit a complexity adjustment. Further, we believe that code combinations should be evaluated each year to determine if they meet the criteria based on the latest hospital billing and utilization data. We also do not believe that it is necessary to provide payment for claims including qualifying code combinations at two APC levels higher than the originating APC or for CMS to pay based on the geometric mean cost of the highest ranking procedure in the qualifying code combination at 100 percent, and then each secondary procedure based on 50 percent of the geometric mean cost of the secondary procedure. We believe that payment at the next higher paying C–APC is adequate for code combinations that exhibit materially greater resource requirements than the primary service and that, in many cases, paying the rate assigned to two levels higher may lead to a significant overpayment. As mentioned previously, we do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. The highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802). Therefore, a policy to pay for claims with qualifying code combinations at two C–APC levels higher than the originating APC is not always feasible. Likewise, while paying 100 percent of the highest ranking procedure and paying 50 percent of the

secondary procedure is the established payment policy under the multiple procedure payment reduction policy that applies to services assigned to status indicator ''T,'' we continue to believe that the established C–APC complexity adjustment policy is appropriate for services assigned to status indicator ''J1'' or ''J2'', and we do not believe that it should be replaced with a multiple procedure payment reduction payment methodology.

In response to the request for an explanation of the cost statistics for the paired ''J1'' code combinations or paired code combinations of ''J1'' services and certain add-on codes evaluated for complexity adjustments, the geometric mean costs of these code combinations shown in Addendum J are calculated using only claims that include these code pairings. As stated previously, the cost of the code combination must exceed twice the cost of the lowest cost-significant procedure within the APC in order for the combination to qualify for a complexity adjustment.

Lastly, as stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59238), we do not believe that it is necessary to adjust the complexity adjustment criteria to allow claims that include a drug or device code, more than two ''J1'' procedures, or procedures performed at certain hospitals to qualify for a complexity adjustment. As mentioned earlier, we believe the current criteria are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service.

After consideration of the public comments we received on the proposed complexity adjustment policy, we are finalizing the C–APC complexity adjustment policy for CY 2019, as proposed, without modification.

(2) Additional C–APCs for CY 2019

For CY 2019 and subsequent years, in the CY 2019 OPPS/ASC proposed rule (83 FR 37062), we proposed to continue to apply the C–APC payment policy methodology made effective in CY 2015 and updated with the implementation of status indicator ''J2'' in CY 2016. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, in the proposed rule (83 FR 37062), we proposed to add three C–APCs under the existing C–APC payment policy beginning in CY 2019: Proposed C–APC 5163 (Level 3 ENT Procedures); proposed C–APC 5183 (Level 3 Vascular Procedures); and proposed C–APC 5184 (Level 4 Vascular Procedures). These APCs were selected to be included in this proposal because, similar to other C–APCs, these APCs include primary, comprehensive services, such as major surgical procedures, that are typically reported with other ancillary and adjunctive services. Also, similar to other APCs that have been converted to C–APCs, there are higher APC levels within the clinical family or related clinical family of these APCs that have previously been assigned to a C–APC. Table 3 of the proposed rule listed the proposed C–APCs for CY 2019. All C–APCs were displayed in Addendum J to the proposed rule (which is available via the internet on the CMS website). Addendum J to the proposed rule also contained all of the data related to the C–APC payment policy methodology, including the list of proposed complexity adjustments and other information.

Comment: Several commenters supported the proposals. Other commenters, including device manufacturer associations, expressed ongoing concerns that the C–APC payment rates may not adequately reflect the costs associated with the services and requested that CMS not establish any additional C–APCs. These commenters also requested that CMS provide an analysis of the impact of the C–APC policy on affected procedures.

Response: We appreciate the commenters' responses. We continue to believe that the proposed C–APCs for CY 2019 are appropriate to be added to the existing C–APC payment policy. We also note that, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59246), we conducted an analysis of the effects of the C–APC policy. The analysis looked at data from CY 2016 OPPS/ASC final rule with comment period, the CY 2017 OPPS/ASC final rule with comment period, and the CY 2018 OPPS/ASC proposed rule, which involved claims data from CY 2014 (before C–APCs became effective) to CY 2016. We looked at separately payable codes that were then assigned to C–APCs and, overall, we observed an increase in claim line frequency, units billed, and Medicare payment for those procedures, which suggest that the C–APC payment policy did not adversely affect access to care or reduce payments to hospitals.

Comment: Several commenters requested that CMS discontinue the C–APC payment policy for several brachytherapy insertion procedures and single session stereotactic radiosurgery procedures, stating concerns that the C–APC methodology does not account for the complexity of delivering radiation therapy and fails to capture appropriately coded claims. The commenters also requested that CMS continue to make separate payments for the 10 planning and preparation codes related to stereotactic radiosurgery (SRS) and include the HCPCS code for IMRT planning (77301) on the list of planning and preparation codes, stating that the service has become more common in single fraction radiosurgery treatment planning.

Response: At this time, we do not believe that it is necessary to discontinue the C–APCs that include brachytherapy insertion procedures and single session SRS procedures. We continue to believe that the C–APC policy is appropriately applied to these surgical procedures for the reasons cited when this policy was first adopted and note that the commenters did not provide any empirical evidence to support their claims that the existing C–APC policy does not adequately pay for these procedures. Also, we will continue in CY 2019 to pay separately for the 10 planning and preparation services (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC based technology when furnished to a beneficiary within 1 month of the SRS treatment for CY 2019 (82 FR 59242 and 59243).

Comment: Several commenters representing stem cell transplant organizations requested that CMS also establish a new C–APC for autologous stem cell transplants for CY 2019. These commenters stated that the C–APC methodology will allow CMS to better capture the costs of additional services, such as laboratory tests, provided with the autologous transplant. The Advisory Panel on Hospital Outpatient Payment (HOP Panel) also recommended that CMS study the appropriateness of creating a comprehensive APC for autologous hematopoietic stem cell transplantation.

Response: We appreciate these comments and may consider the creation of a C–APC for autologous stem cell transplants for future rulemaking as recommended by the HOP Panel.

Comment: Two manufacturers of drugs used in ocular procedures requested that CMS discontinue the C–APC payment policy for existing C–APCs that include procedures involving

their drugs and instead provide separate payment for the drugs. The manufacturer commenters, as well as several physicians, believed that the C–APC packaging policy, which packages payment for certain drugs that are adjunctive to the primary service, results in underpayment for the drugs.

Response: We continue to believe that the procedures assigned to the proposed C–APCs, including the procedures involving the drugs used in ocular procedures mentioned by the commenters, are appropriately paid through a comprehensive APC and the costs of drugs (as well as other items or services furnished with the procedures) are reflected in hospital billing, and therefore the rates that are established for the ocular procedures. As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584), procedures assigned to C–APCs are primary services (mostly major surgical procedures) that are typically the focus of the hospital outpatient stay. In addition, with regard to the packaging of the drugs based on the C–APC policy, as stated in previous rules (78 FR 74868 through 74869 and 74909 and 79 FR 66800), items included in the packaged payment provided with the primary ''J1'' service include all drugs, biologicals, and radiopharmaceuticals payable under the OPPS, regardless of cost, except those drugs with pass-through payment status.

After consideration of the public comments we received, we are finalizing the proposed C–APCs for CY 2019. Table 7 below lists the final C–APCs for CY 2019. All C–APCs are displayed in Addendum J to this final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2019.

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TABLE 7.—CY 2019 C-APCs

C-APC	CY 2019 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	*
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5183	Level 3 Vascular Procedures	VASCX	*
5184	Level 4 Vascular Procedures	VASCX	*
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	

C-APC	CY 2019 APC Group Title	Clinical Family	New C-APC
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.

BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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(3) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. When a procedure assigned to a New Technology APC is included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service is typically packaged into the payment for the primary procedure. Because the new technology service is not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service is reduced. This is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

For example, for CY 2017, there were seven claims generated for HCPCS code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy), which involves the use of the Argus® II Retinal Prosthesis System. However, several of these claims were not available for ratesetting because HCPCS code 0100T was reported with a ''J1'' procedure and, therefore, payment was packaged into the associated C–APC payment. If these services had been separately paid under the OPPS, there would be at least two additional single claims available for ratesetting. As mentioned previously, the purpose of the new technology APC policy is to ensure that there are sufficient claims data for new services, which is particularly important for services with a low volume such as procedures described by HCPCS code 0100T. Another concern is the costs reported for the claims when payment is not packaged for a new technology procedure may not be representative of all of the services included on a claim that is generated, which may also affect our ability to assign the new service to the most appropriate clinical APC.

To address this issue and help ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC proposed rule (83 FR 37063), we proposed to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. This issue is also addressed in section III.C.3.b. of the proposed rule and this final rule with comment period.

Comment: Numerous commenters supported the proposal.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing the proposal, without modification, to exclude payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC.

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to

calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37064), for CY 2019 and subsequent years, we proposed to continue our composite APC payment policies for mental health services and multiple imaging services, as discussed below. In addition, as discussed in section II.A.2.b.(3) and II.A.2.c. of the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33577 through 33578 and 59241 through 59242 and 59246, respectively), in the CY 2019 proposed rule, we proposed to continue to assign CPT code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator ''J1'' and to continue to assign the services described by CPT code 55875 to C–APC 5375 (Level 5 Urology and Related Services) for CY 2019. We did not receive any public comments on these proposed assignments. Therefore, for CY 2019, we are continuing to assign CPT code 55875 to status indicator ''J1'' and to assign services described by CPT code 55875 to C–APC 5375.

(1) Mental Health Services Composite APC

In the CY 2019 OPPS/ASC proposed rule (83 FR 37064), we proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1 Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level 2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37064), for CY 2019, we proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2019. In addition, we proposed to set the proposed payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

Comment: One commenter supported equalizing payments between the outpatient APC rate and the PHP per diem rate. The commenter also supported the increase in the proposed CY 2019 payment rates from the CY 2018 payment rates.

Response: We appreciate the commenter's support.

After consideration of the public comment we received, we are finalizing our CY 2019 proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 for CY 2019. In addition, we are finalizing our CY 2019 proposal, without modification, to set the payment rate for composite APC 8010 at the same payment rate as APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the payment rate for composite APC 8010.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, in order to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance

imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37065), we proposed, for CY 2019 and subsequent years, to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We stated that we continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2019 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from a partial year of CY 2017 claims available for the CY 2019 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), were identified by asterisks in Addendum N to the CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and were discussed in more detail in section II.A.1.b. of the CY 2019 OPPS/ASC proposed rule.

For the CY 2019 OPPS/ASC proposed rule, we were able to identify approximately 638,902 ''single session'' claims out of an estimated 1.7 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 37 percent of all eligible claims, to calculate the proposed CY 2019 geometric mean costs for the multiple imaging composite APCs. Table 4 of the CY 2019 OPPS/ASC proposed rule listed the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2019.

We did not receive any public comments on these proposals. However, in the CY 2019 OPPS/ASC proposed rule (83 FR 37065), we inadvertently omitted the new CPT codes that will be effective January 1, 2019 from Table 4. We did include these codes in Addendum M to the proposed rule (which was available via the internet on the CMS website). Therefore, new Category I CPT codes that will be effective January 1, 2019 are flagged with comment indicator ''NI'' in Addendum M to this CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim APC assignment for CY 2019. We are inviting public comments in this CY 2019 OPPS/ASC final rule with comment period on the interim APC assignments and payment rates for the new codes in Addendum M that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

Table 8 below lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2019.

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TABLE 8.—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
CY 2019 APC 8004 (Ultrasound Composite)	**CY 2019 Approximate APC Geometric Mean Cost = $302**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Use 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2019 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2019 Approximate APC Geometric Mean Cost = $267**
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74261	Ct colonography, w/o dye
74176	Ct angio abd & pelvis
CY 2019 APC 8006 (CT and CTA with Contrast Composite)	**CY 2019 Approximate APC Geometric Mean Cost = $485**
70487	Ct maxillofacial w/dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye

70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2019 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2019 Approximate APC Geometric Mean Cost = $549**
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye

70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
CY 2019 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2019 Approximate APC Geometric Mean Cost = $863**
70549	Mr angiograph neck w/o & w/dye
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye

72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient. The OPPS packages payments

for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which often occurs if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2019, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment of the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In the CY 2019 OPPS/ASC proposed rule (83 37067 through 37071), for CY 2019, we proposed to conditionally package the costs of selected newly identified ancillary services into payment with a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the proposed and finalized changes to the packaging policies beginning in CY 2019.

b. CY 2019 Packaging Policy for Non-Opioid Pain Management Treatments

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device. We stated in the CY 2018 OPPS/ASC final rule with comment period that CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [3] included a recommendation for CMS to ''. . . review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . .'' [4] With respect to the packaging policy, the Commission's report states that ''. . . the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital-administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon

[3] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[4] Ibid, at page 57, Recommendation 19.

administers a non-opioid medication or not.'' [5] HHS also presented an Opioid Strategy in April 2017 [6] that aims in part to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the opioid crisis was declared a national public health emergency under Federal law [7] and this determination was renewed on April 20, 2018.[8]

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37068 through 37071), in response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. The costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with specific drugs that function as a supply over a 5-year time period (CYs 2013 through 2017) to determine whether this packaging policy has reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products. We did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis.

In fact, under the OPPS, we observed the opposite effect for several drugs that function as a supply, including Exparel (HCPCS code C9290). Exparel is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel was approved by the FDA for administration into the postsurgical site to provide postsurgical analgesia.[9] Exparel had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel was packaged as a surgical supply under both the OPPS and the ASC payment system. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From CYs 2013 through 2017, there was an overall increase in the OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from CYs 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we stated in the CY 2019 OPPS/ASC proposed rule that we did not believe that changes were necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we stated that we considered Exparel to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain. We also stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), we reiterated our position with regard to payment for Exparel, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document [10] submitted for the FDA Advisory Committee Meeting held February 14–15, 2018, by the manufacturer of Exparel that notes that ''. . . Bupivacaine, the active pharmaceutical ingredient in Exparel, is a local anesthetic that has been used for infiltration/field block and peripheral nerve block for decades'' and that ''since its approval, Exparel has been used extensively, with an estimated 3.5 million patient exposures in the US.'' [11] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[12] Therefore, we also stated in the CY 2019 OPPS/ASC proposed rule that, based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we did not believe that the OPPS packaging policy had discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, we invited public comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in

[5] Ibid.

[6] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[7] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[8] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[9] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

[10] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[11] Ibid, page 9.

[12] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

opioid use and addiction among Medicare beneficiaries.

Comment: Several commenters, including hospital associations, medical specialty societies, and drug manufacturers, requested that CMS pay separately for Exparel in the hospital outpatient setting. Some of these commenters noted that Exparel is used more frequently in this setting and the use of non-opioid pain management treatments should also be encouraged in the hospital outpatient department. The manufacturer of Exparel, Pacira Pharmaceuticals, stated that since the drug became packaged in 2015, utilization of the drug in the hospital outpatient department has remained flat while the opioid crisis has continued to worsen. The manufacturer suggested that, to address the opioid crisis among Medicare beneficiaries, CMS should promote ''increased penetration of non-opioid therapies in the HOPD setting—or in other words, higher rates of usage of non-opioid treatments for the same number of surgical procedures.''

Response: While these commenters advocated paying separately for Exparel in the hospital outpatient setting, we do not believe that there is sufficient evidence that non-opioid pain management drugs should be paid separately in the hospital outpatient setting at this time. The commenters submitted some peer-reviewed studies, discussed in further detail below, that showed that the use of Exparel could lead to a decrease in opioid use in the treatment of acute post-surgical pain among Medicare beneficiaries. However, the commenters did not provide evidence that the OPPS packaging policy for Exparel (or other non-opioid drugs) creates a barrier to use of Exparel in the hospital setting. Further, while we received some public comments suggesting that, as a result of using Exparel in the OPPS setting, providers may prescribe fewer opioids for Medicare beneficiaries, we do not believe that the OPPS payment policy presents a barrier to use of Exparel or affects the likelihood that providers may prescribe fewer opioids in the HOPD setting. Several drugs are packaged under the OPPS and payment for such drugs is included in the payment for the associated primary procedure. We were not persuaded by the anecdotal information supplied by commenters suggesting that some providers avoid use of non-opioid alternatives (including Exparel) solely because of the OPPS packaged payment policy. Finally, while the rate of growth for Exparel use in the HOPD setting has declined over recent years, such trend might be expected because absolute utilization tends to be smaller in the initial period when a drug first comes available on the U.S. market. Additionally, we observed that the total number of providers billing for Exparel under the OPPS has increased each year from 2012 to 2017. Therefore, we do not believe that the current OPPS payment methodology for Exparel and other non-opioid pain management drugs presents a barrier to their use.

In addition, higher use in the hospital outpatient setting not only supports the notion that the packaged payment for Exparel is not causing an access to care issue, but also that the payment rate for primary procedures in the HOPD using Exparel adequately reflects the cost of the drug. That is, because Exparel is commonly used and billed under the OPPS, the APC rates for the primary procedures reflect such utilization. Therefore, the higher utilization in the OPPS setting should mitigate the need for separate payment. We remind readers that the OPPS is a prospective payment system, not a cost-based system and, by design, is based on a system of averages whereby payment for certain cases may exceed the costs incurred, while for others, it may not. As stated earlier in this section, the OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. We will continue to analyze the evidence and monitor utilization of non-opioid alternatives in the OPD and ASC settings for potential future rulemaking.

We also stated in the proposed rule that, although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of CYs 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment period ended for Exparel at the end of CY 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between CYs 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of CYs 2013 and 2014 when the drug received pass-through payments, indicating that the payment rate of ASP+6 percent for Exparel may have had an impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference in utilization and claims reporting between the hospital outpatient department and the ASC setting, one potential explanation is that, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may impact these providers more acutely than hospital outpatient departments, and therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Another possible contributing factor is that ASCs do not typically report packaged items and services and, accordingly, our analysis may be undercounting the number of Exparel units utilized in the ASC setting.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, we stated in the proposed rule that we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we stated that we believe it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, we proposed in section XII.D.3. of the CY 2019 OPPS/ASC

proposed rule to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019 (83 FR 37065).

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. The packaging policies established under the OPPS also typically apply when services are provided in the ASC setting, and the policies have the same strategic goals in both settings. While the CY 2019 proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we stated in the proposed rule that we believe that the proposed change will incentivize the use of non-opioid pain management drugs and is responsive to the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, with the overall goal of combating the current opioid addiction crisis. As previously noted, a discussion of the CY 2019 proposal for payment of non-opioid pain management drugs in the ASC setting was presented in further detail in section XII.D.3. of the proposed rule, and we refer readers to section XII.D.3. of this CY 2019 OPPS/ASC final rule with comment period for further discussion of the final policy for CY 2019. We also stated in the CY 2019 OPPS/ASC proposed rule that we were interested in peer-reviewed evidence that demonstrates that use of non-opioid alternatives, such as Exparel, furnished in the outpatient setting actually does lead to a decrease in prescription opioid use and addiction and invited public comments containing evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

Comment: Several commenters, including individual stakeholders, hospital and physician groups, national medical associations, drug rehabilitation specialists, device manufacturers, and groups representing the pharmaceutical industry, supported the proposal to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies, such as Exparel, in the ASC setting for CY 2019. These commenters believed that packaged payment for non-opioid alternatives presents a barrier to care and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic.

Other commenters, including MedPAC, did not support this proposal and stated that the policy was counter to the OPPS packaging policies created to encourage efficiencies and could set a precedent for unpackaging services. One commenter stated that Exparel is more costly, but not more effective than bupivacaine, a less costly non-opioid alternative. Other commenters expressed concerns that the proposal may have the unintended consequence of limiting access to opioid prescriptions for beneficiaries for whom an opioid prescription would be appropriate. The commenters noted that some non-opioid pain management treatments may pose other risks for patients and patient safety.

Response: This comment and other comments specific to packaging under the ASC payment system are addressed in section XII.D.3. of this final rule with comment period.

In addition, as noted in section XII.D.3. of the proposed rule (83 FR 37065 through 37068), we sought comments on whether the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may warrant separate payment. For example, we stated we were interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and/or reduced cases of associated opioid addiction following such an outpatient visit or procedure. We also requested comments that provide evidence (such as published peer-reviewed literature) we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and, therefore, warrants separate payment under either or both the OPPS and the ASC payment system. We stated that any evidence demonstrating the reduction or avoidance of prescription opioids would be the criterion we use to determine whether separate payment is warranted for CY 2019. We also stated that if evidence changes over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

Comment: With regard to whether the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure and supportive evidence of these reductions, one commenter, the manufacturer of Exparel, submitted studies that claimed that the use of Exparel by Medicare patients undergoing total knee replacement procedures reduced prescription opioid consumption by 90 percent compared to the control group measured at 48 hours post-surgery.[13] The manufacturer submitted additional studies claiming statistically significant reductions in opioid use with the use of Exparel for various surgeries, including laparotomy, shoulder replacement, and breast reconstruction.

Several commenters identified other non-opioid pain management drugs that they believe decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) and may warrant separate payment for CY 2019. Commenters from the makers of other packaged non-opioid pain management drugs, including a non-opioid intrathecal infusion drug indicated for the management of severe chronic pain, submitted supporting studies which claimed that the drug reduced opioid use in patients with chronic pain.

Several commenters, from hospitals, hospital associations, and clinical specialty organizations, requested separate payment for IV acetaminophen, IV ibuprofen, and epidural steroid injections. In addition, one commenter, the manufacturer of a non-opioid analgesic containing bupivacaine hcl not currently approved by FDA, requested clarification regarding whether the proposal would also apply to this drug once it receives FDA approval. Several commenters requested separate payment for a drug that treats postoperative pain after cataract surgery, currently has drug pass-through payment status, and therefore is not packaged under the OPPS or the ASC payment system. The commenters requested that CMS explicitly state that this drug will also be paid for separately in the ASC setting after pass-through

[13] Michael A. Mont et al., Local Infiltration Analgesia With Liposomal Bupivacaine Improves Pain Scores and Reduces Opioid Use After Total Knee Arthroplasty: Results of a Randomized Controlled Trial. J. of Arthroplasty (2018).

payment status ends for the drug in 2020. Lastly, one commenter, the makers of a diagnostic drug that is not a non-opioid, requested separate payment.

Response: We appreciate these comments. After reviewing the studies provided by the commenters, we continue to believe the separate payment is appropriate for Exparel in the ASC setting. At this time, we have not found compelling evidence for other non-opioid pain management drugs described above to warrant separate payment under the ASC payment system for CY 2019. Also, with regard to the requests for CMS to confirm that the proposed policy would also apply in the future to certain non-opioid pain management drugs, we reiterate that the proposed policy is for CY 2019 and is applicable to non-opioid pain management drugs that are currently packaged under the policy for drugs that function as a surgical supply when used in the ASC setting, which currently is only Exparel. To the extent that other non-opioid pain management drugs become available on the U.S. market in 2019, this policy would also apply to those drugs.

As noted above, we stated in the proposed rule that we were interested in comments regarding other non-opioid treatments besides Exparel that might be affected by our OPPS and ASC packaging policies, including alternative, non-opioid pain management treatments, such as devices or therapy services that are not currently separable payable. We stated that we were specifically interested in comments regarding whether CMS should consider separate payment for items and services for which payment is currently packaged under the OPPS and the ASC payment system that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use and/or addiction during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. As previously stated, we intended to examine the evidence submitted to determine whether to adopt a final policy in this final rule with comment period that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and/or addiction following an outpatient visit or procedure. We stated that some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We indicated in the proposed rule that we also were interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. We stated that this could include, for example, spinal cord stimulators used to treat chronic pain, such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463 and 5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and the ASC payment system unless they have pass-through payment status. However, we stated in the proposed rule that, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we were interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time, would also incentivize the use of alternative non-opioid pain management treatments and improve access to non-opioid alternatives, particularly for innovative and low-volume items and services.

We also stated that we were interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. For example, we stated in the proposed rule that we were considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device, or service would be appropriate. We indicated that, to the extent that commenters provided evidence to support this approach, we would consider adopting a final policy in this final rule with comment period, which could include regulatory changes that would allow for an exception to the packaging of certain nonpass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions and/or opioid abuse or misuse during or after an outpatient visit or procedure to effectuate such change.

Comment: Several commenters, manufacturers of spinal cord stimulators (SCS), stated that separate payment was also warranted for these devices because they provide an alternative treatment option to opioids for patients with chronic, leg, or back pain. One of the manufacturers of a high-frequency SCS device provided supporting studies which claimed that patients treated with their device reported a statistically significant average decrease in opioid use compared to the control group.[14] This commenter also submitted data that showed a decline in the mean daily dosage of opioid medication taken and that fewer patients were relying on opioids at all to manage their pain when they used the manufacturer's device.[15] Another commenter, a SCS manufacturer, stated that there are few peer-reviewed studies that evaluate opioid elimination and/or reduction following SCS and that there is a need for more population-based research with opioid reduction or elimination as a study endpoint. However, this commenter believed that current studies suggest that opioid use may be reduced following SCS therapy.

Commenters representing various stakeholders requested separate payments for various non-opioid pain management treatments, such as

[14] Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Brown LL, Yearwood TL, Bundschu R, Burton AW, Yang T, Benyamin R, Burgher AH. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: The SENZA–RCT randomized controlled trial, *Anesthesiology.* 2015 Oct;123(4):851–60.

[15] Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med.* 2014 Mar; 15(3):347–54.

continuous nerve blocks (including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical site or nerve), cooled thermal radiofrequency ablation for nonsurgical, chronic nerve pain, and physical therapy services. These commenters, including national hospital associations, recommended that while ''certainly not a solution to the opioid epidemic, unpackaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-standing practice patterns without major negative consequences.'' This same commenter suggested that Medicare consider separate payment for Polar ice devices for postoperative pain relief after knee procedures. The commenter also noted that therapeutic massage, topically applied THC oil, acupuncture, and dry needling procedures are very effective therapies for relief of both postoperative pain and long-term and chronic pain.

Commenters suggested various mechanisms through which separate payment or a higher-paying APC assignment for the primary service could be made. Commenters offered reports, studies, and anecdotal evidence of varying degrees to support why the items or services about which they were writing offered an alternative to or reduction of the need for opioid prescriptions.

Response: We appreciate the detailed responses to our solicitation for comments on this topic. We plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid and/or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. We note that some of the items and services mentioned by commenters are not covered by Medicare, and we do not intend to establish payment for noncovered items and services. We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system that will encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or opioid abuse or misuse during or after an outpatient visit or procedure.

Comment: One commenter suggested that CMS provide separate payment for HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) in the hospital outpatient department setting and the ASC setting following a post-surgery procedure. This commenter explained that if a patient needs additional pain relief 3 to 5 days post-surgery, a facility cannot receive payment for providing a replacement disposable drug delivery system (HCPCS code A4306) unless the entire continuous nerve block procedure is performed. This commenter believed that CMS should allow for HCPCS code A4306 to be dispensed to the patient as long as the patient is in pain, the pump is empty, and the delivery catheters are still in place. The commenter believed that the drug delivery system should incentivize the continued use of non-opioid alternatives when needed. In addition, several commenters stated that CMS should use an equitable payment adjustment under our authority at section 1833(t)(2)(E) of the Act to establish add-on payments for packaged devices used as non-opioid alternatives.

Response: We appreciate the commenter's suggestion. We acknowledge that use of these items may help in the reduction of opioid use postoperatively. However, we note that packaged payment of such an item does not prevent the use of these items. We remind readers that payment for packaged items is included in the payment for the primary service. We share the commenter's concern about the need to reduce opioid use and will take the commenter's suggestion into consideration for future rulemaking.

After reviewing the non-opioid pain management alternatives suggested by the commenters as well as the studies and other data provided to support the request for separate payment, we have not determined that separate payment is warranted at this time for any of the non-opioid pain management alternatives discussed above.

We also invited public comments on whether a reorganization of the APC structure for procedures involving non-opioid products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we stated we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we also invited comments on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management.

Furthermore, because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we stated that we were interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy. We also stated that the implications of incentivizing use of non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are of interest. The goal is to encourage appropriate use of such non-opioid alternatives. As previously stated, this comment solicitation is also discussed in section XII.D.3. of this final rule with comment period relating to the ASC payment system.

Comment: Regarding APC reorganization, one commenter suggested that CMS restructure the two-level Nerve Procedure APCs (5431 and 5432) to provide more payment granularity for the procedures included in the APCs by creating a third level.

Response: This comment is addressed in section III.D.17. of this final rule with comment period. As stated in that section, we believe that the current two-level APCs for the Nerve Procedures provide an appropriate distinction between the resource costs at each level and provide clinical homogeneity. We will continue to review this APC structure to determine if additional granularity is necessary for this APC family in future rulemaking. In addition, we believe that more analysis of such groupings is necessary before adopting such change.

In addition, in the proposed rule, we invited the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program. We stated that we were interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over

Paperwork'' Initiative, we stated that we were interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

Comment: Several commenters addressed payment barriers that may inhibit access to non-opioid pain management treatments previously discussed throughout this section. With regard to barriers related to payment methodologies or coverage, one commenter, a clinical specialty society, suggested that CMS support multi-modal pain management and enhanced recovery after surgery (ERAS) and encourage patient access to certified registered nurse anesthetist (CRNA) pain management. One commenter also suggested that CMS reduce cost-sharing and eliminate the need for prior authorization for non-opioid pain management strategies.

Response: We appreciate the various, insightful comments we received from stakeholders regarding barriers that may inhibit access to non-opioid alternatives for pain treatment and management in order to more effectively address the opioid epidemic. Many of these comments have been previously addressed throughout this section.

After consideration of the public comments that we received, we are finalizing the proposed policy, without modification, to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We will continue to analyze the issue of access to non-opioid alternatives in the OPD and the ASC settings as we implement section 6082 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271 enacted on October 24, 2018. This policy is also discussed in section XII.D.3 of this final rule with comment period.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59255 through 59256), we applied this policy and calculated the relative payment weights for each APC for CY 2018 that were shown in Addenda A and B to that final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2019, as we did for CY 2018, in the CY 2019 OPPS/ASC proposed rule (83 FR 37071), we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2019 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2019, as we did for CY 2018, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2019, as we did for CY 2018, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We did not receive any public comments on our proposal to continue to use the geometric mean cost of APC 5012 to standardize relative payment weights for CY 2019. Therefore, we are finalizing our proposal and assigning APC 5012 the relative payment weight of 1.00, and using the relative payment weight for APC 5012 to derive the unscaled relative payment weight for each APC for CY 2019.

We note that, in section X.B. of the OPPS/ASC proposed rule (83 FR 37137 through 37138) and of this final rule with comment period, we discuss our CY 2019 proposal and established final policy to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at an amount of 70 percent of the OPPS rate for a clinic visit service in CY 2019, rather than at the standard OPPS rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the proposal and final policy have only a negligible effect on the scalar. Specifically, under the proposed and final policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under our proposed and final policy, the savings that will result from the change in payments for these clinic visits will not be budget neutral. Therefore, the impact of the proposed and final policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. We refer readers to section X.B. of this CY 2019 OPPS/ASC final rule with comment period for further discussion of this final policy.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2019 is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To comply with this requirement concerning the APC changes, in the CY 2019 OPPS/ASC proposed rule (83 FR 37071 through 37072), we proposed to compare the estimated aggregate weight using the CY 2018 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2019 unscaled relative payment weights.

For CY 2018, we multiplied the CY 2018 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2017 claims to calculate the total relative payment weight for

each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2019, we proposed to apply the same process using the estimated CY 2019 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2018 estimated aggregate weight by the unscaled CY 2019 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2019 OPPS final rule link and open the claims accounting document link at the bottom of the page.

We proposed to compare the estimated unscaled relative payment weights in CY 2019 to the estimated total relative payment weights in CY 2018 using CY 2017 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2019 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2019 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4553 to ensure that the proposed CY 2019 relative payment weights are scaled to be budget neutral. The proposed CY 2019 relative payment weights listed in Addenda A and B to the proposed rule (which are available via the internet on the CMS website) were scaled and incorporated the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this final rule with comment period) is included in the budget neutrality calculations for the CY 2019 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2019. Using updated final rule claims data, we are updating the estimated CY 2019 unscaled relative payment weights by multiplying them by a weight scalar of 1.4574 to ensure that the final CY 2019 relative payment weights are scaled to be budget neutral.

The final CY 2019 relative payments weights listed in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. As stated in the CY 2019 OPPS/ASC proposed rule, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2017 forecast of the FY 2019 market basket increase, the proposed FY 2019 IPPS market basket update was 2.8 percent. However, sections 1833(t)(3)(F) and 1833(t)(3)(G)(v) of the Act, as added by section 3401(i) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) and as amended by section 10319(g) of that law and further amended by section 1105(e) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), provide adjustments to the OPD fee schedule increase factor for CY 2019.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment, and then revised this methodology as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the CY 2019 OPPS/ASC proposed rule (83 FR 37072), the proposed MFP adjustment for FY 2019 was 0.8 percentage point.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37072), we proposed that if more recent data became subsequently available after the publication of the proposed rule (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2019 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in this CY 2019 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(3)(F)(ii) of the Act requires that, for each of years 2010 through 2019, the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act be reduced by the adjustment described in section 1833(t)(3)(G) of the Act. For CY 2019, section 1833(t)(3)(G)(v) of the Act provides a 0.75 percentage point reduction to the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act. Therefore, in accordance with sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act, in the CY 2019 OPPS/ASC proposed rule, we proposed to apply a 0.75 percentage point reduction to the OPD fee schedule increase factor for CY 2019.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we are applying an OPD fee schedule increase factor of 1.35 percent for the CY 2019 OPPS (which is 2.9 percent, the final estimate of the hospital inpatient market basket percentage increase, less the final 0.8 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment).

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to

calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2019 OPPS/ASC proposed rule, we proposed to amend 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the requirement in section 1833(t)(3)(F)(i) of the Act that, for CY 2019, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS, and to reflect the requirement in section 1833(t)(3)(G)(v) of the Act, as required by section 1833(t)(3)(F)(ii) of the Act, that we reduce the OPD fee schedule increase factor by an additional 0.75 percentage point for CY 2019.

To set the OPPS conversion factor for the CY 2019 OPPS/ASC proposed rule, we proposed to increase the CY 2018 conversion factor of $78.636 by 1.25 percent (83 FR 37073). In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2019 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0004 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2019 IPPS wage indexes to those payments using the FY 2018 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2019 OPPS/ASC proposed rule, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of the proposed rule and this final rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

For the CY 2019 OPPS/ASC proposed rule, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of the proposed rule and this final rule with comment period. We proposed to calculate a CY 2019 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2019 payments under section 1833(t) of the Act, including the proposed CY 2019 cancer hospital payment adjustment, to estimated CY 2019 total payments using the CY 2018 final cancer hospital payment adjustment as required under section 1833(t)(18)(B) of the Act. The CY 2019 proposed estimated payments applying the proposed CY 2019 cancer hospital payment adjustment were the same as estimated payments applying the CY 2018 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 16002(b) of the 21st Century Cures Act, we stated in the proposed rule that we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are applying as stated in section II.F. of the proposed rule.

For the CY 2019 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2019 would equal approximately $126.7 million, which represented 0.17 percent of total projected CY 2019 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.04 percent estimate of pass-through spending for CY 2018 and the 0.17 percent estimate of proposed pass-through spending for CY 2019, resulting in a proposed decrease for CY 2019 of 0.13 percent. Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2019. We estimated for the proposed rule that outlier payments would be 1.02 percent of total OPPS payments in CY 2018; the 1.00 percent for proposed outlier payments in CY 2019 would constitute a 0.02 percent increase in payment in CY 2019 relative to CY 2018.

For the CY 2019 OPPS/ASC proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of -0.75 percent (that is, the proposed OPD fee schedule increase factor of 1.25 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2019 of $77.955 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.591 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2019, we proposed to amend § 419.32(b)(1)(iv)(B) by adding a new paragraph (*10*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2019 to satisfy the statutory requirements of sections 1833(t)(3)(F) and (t)(3)(G)(v) of the Act. We proposed to use a reduced conversion factor of $77.955 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.591 in the conversion factor relative to hospitals that met the requirements).

For CY 2019, we proposed to use a conversion factor of $79.546 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 1.25 percent for CY 2019, the required proposed wage index budget neutrality adjustment of approximately 1.0004, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of -0.13 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2019 of $79.546.

We invited public comments on these proposals. However, we did not receive any public comments. Therefore, we are finalizing these proposals without modification. For CY 2019, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act (discussed in section II.F. of this final rule with comment period). Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.88 for CY 2018, is 0.88 for CY 2019. As a result, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2019 OPPS is 1.35 percent (which reflects the 2.9 percent final estimate of the hospital inpatient market basket percentage increase, less the final 0.8 percentage point MFP adjustment, and less the 0.75 percentage point additional adjustment). For CY 2019, we are using a conversion factor of $79.490 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 1.35 percent for CY 2019, the required wage index budget neutrality adjustment of

approximately 0.9984, and the adjustment of -0.10 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2019 of $79.490.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of this final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). In the CY 2019 OPPS/ASC proposed rule (83 FR 37073), we proposed to continue this policy for the CY 2019 OPPS. We refer readers to section II.H. of this final rule with comment period for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

We did not receive any public comments on this proposal. Therefore, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37073), we are finalizing our proposal, without modification, to continue this policy as discussed above for the CY 2019 OPPS.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website), for estimating APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2019 pre-reclassified wage index that the IPPS uses to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (c)(3) of our regulations. For the CY 2019 OPPS, we proposed to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00 (as discussed below and in the CY 2019 OPPS/ASC proposed rule (83 FR 37074 through 37076), we proposed not to extend the imputed floor under the OPPS for CY 2019 and subsequent years, consistent with our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 and 20363) not to extend the imputed floor under the IPPS for FY 2019 and subsequent fiscal years). Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. In the CY 2019 OPPS/ASC proposed rule (83 FR 37074), we referred readers to the FY 2011 through FY 2018 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: For FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; and for FY 2018, 82 FR 38142.

We did not receive any public comments on this proposal. Therefore, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37074), we are finalizing our proposal to implement the frontier State floor under the OPPS in the same manner as we have since CY 2011.

In addition to the changes required by the Affordable Care Act, we note that the FY 2019 IPPS wage indexes continue to reflect a number of adjustments implemented over the past few years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, and an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment). We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) and final rule (83 FR 41362 through 41390) for a detailed discussion of all proposed and final changes to the FY 2019 IPPS wage indexes. We note that, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to apply the imputed floor to the IPPS wage index computations for FY 2019 and subsequent fiscal years. Consistent with this, we proposed in the CY 2019 OPPS/ASC proposed rule (83 FR 37074) not to extend the imputed floor policy under the OPPS beyond December 31, 2018 (the date the imputed floor policy is set to expire under the OPPS). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41376 through 41380), we finalized our proposal to not extend the imputed floor policy under the IPPS. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41376 through 41380) for a detailed discussion of our rationale for discontinuing the imputed floor under the IPPS.

Summarized below are the comments we received regarding our proposal to discontinue the imputed floor under the OPPS, along with our response.

Comment: Several commenters agreed with the proposal not to extend the imputed floor policy under the OPPS beyond December 31, 2018.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37074), consistent with the FY 2019 IPPS/LTCH PPS final rule, we are finalizing our proposal not to extend the imputed floor policy under the OPPS beyond December 31, 2018.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes. We believe that it is important for the OPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to the statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB Bulletin No. 17–01 is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), we noted that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index, ratesetting, and Tables 2 and 3 associated with the FY 2019 IPPS/LTCH PPS proposed rule. We stated that this new CBSA may affect the IPPS budget neutrality factors and wage indexes, depending on whether the area is eligible for the rural floor and the impact of the overall payments of the hospital located in this new CBSA. As we did in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20354), in the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we provided an estimate of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 IPPS wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 was calculated using the average hourly wage data for one provider (provider 130002).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we provided the proposed FY 2019 IPPS unadjusted and occupational mix adjusted national average hourly wages and the estimated CBSA average hourly wages. Taking the estimated average hourly wage of new CBSA 46300 and dividing by the proposed national average hourly wage resulted in the estimated wage indexes shown in the table in the proposed rule (83 FR 37075), which is also provided below.

	Estimated Unadjusted Wage Index for New CBSA 46300	**Estimated Occupational Mix Adjusted Wage Index for New CBSA 46300**
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

As we stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41363), for the FY 2019 IPPS wage indexes, we used the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01, and incorporated the revision from OMB Bulletin No. 17–01 in the final FY 2019 IPPS wage index, ratesetting, and tables. Similarly, in the CY 2019 OPPS/ASC proposed rule (82 FR 37075), for the proposed CY 2019 OPPS wage indexes, we proposed to use the OMB

delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01, and stated that we would incorporate the revision from OMB Bulletin No. 17–01 in the final CY 2019 OPPS wage index, ratesetting, and tables.

We did not receive any public comments on our proposals. Accordingly, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37074 through 37075), we are finalizing the proposal, without modification, to use the OMB delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01, and have incorporated the revision from OMB Bulletin No. 17–01 in the final CY 2019 OPPS wage index, ratesetting, and tables.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes for the purposes of crosswalking counties to CBSAs for the OPPS wage index.

The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html*. In our transition to using only FIPS codes for counties for the IPPS wage index, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we updated the FIPS codes used for crosswalking counties to CBSAs for the IPPS wage index effective October 1, 2017, to incorporate changes to the counties or county equivalent entities included in the Census Bureau's most recent list. We included these updates to calculate the area IPPS wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59261), we finalized our proposal to implement these FIPS code updates for the OPPS wage index effective January 1, 2018, beginning with the CY 2018 OPPS wage indexes.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we proposed to use the FY 2019 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2019. Therefore, we stated in the proposed rule that any adjustments for the FY 2019 IPPS post-reclassified wage index would be reflected in the final CY 2019 OPPS wage index. (We refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20353 through 20377) and final rule (83 FR 41362 through 41390), and the proposed and final FY 2019 hospital wage index files posted on the CMS website.) We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37075) that we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Summarized below are the comments we received regarding this proposal, along with our response.

Comment: Several commenters opposed applying a budget neutrality adjustment for the rural floor under the OPPS on a national basis. The commenters believed applying budget neutrality on a national basis disadvantages hospitals in most States while benefiting hospitals in a few States that have taken advantage of the system where a rural hospital has a wage index higher than most or all urban hospitals in a State. The commenters stated that rural floor budget neutrality currently requires all wage indexes for hospitals throughout the Nation to be reduced. However, the commenters added, hospitals in those States that have higher wage indexes because of the rural floor are not substantially affected by the wage index reductions. One of the commenters supported calculating rural floor budget neutrality under the OPPS for each individual State.

Response: We appreciate these comments. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59259), we acknowledge that the application of the wage index and applicable wage index adjustments to OPPS payment rates may create distributional payment variations, especially within a budget neutral system. However, we continue to believe it is reasonable and appropriate to continue the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS. We believe that hospital inpatient and outpatient departments are subject to the same labor cost environment, and therefore, the wage index and any applicable wage index adjustments (including the rural floor and rural floor budget neutrality) should be applied in the same manner under the IPPS and OPPS. Furthermore, we believe that applying the rural floor and rural floor budget neutrality in the same manner under the IPPS and OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In addition, we believe the application of different wage indexes and wage index adjustments under the IPPS and OPPS would add a level of administrative complexity that is overly burdensome and unnecessary. Therefore, we are continuing the current policy of applying budget neutrality for the rural floor under the OPPS on a national basis, consistent with the IPPS.

After consideration of the public comments we received, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we are finalizing our proposal, without modification, to use the FY 2019 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2019. Therefore, any adjustments for the FY 2019 IPPS post-reclassified wage index are reflected in the final CY 2019 OPPS wage index. As stated earlier, we continue to believe that using the final fiscal year IPPS post-reclassified wage index, inclusive of any adjustments, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount is reasonable and logical, given the

inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we proposed to continue this policy for CY 2019, and included a brief summary of the major proposed FY 2019 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2019, which we have summarized below. We invited public comments on these proposals. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390) for a detailed discussion of the changes to the FY 2019 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For CY 2019, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA).

We did not receive any public comments on these proposals. Therefore, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37075 through 37076), we are finalizing these proposals without modification.

As stated earlier, in the FY 2015 IPPS/LTCH PPS final rule, we adopted the OMB labor market area delineations issued by OMB in OMB Bulletin No. 13–01 on February 28, 2013, based on standards published on June 28, 2010 (75 FR 37246 through 37252) and the 2010 Census data to delineate labor market areas for purposes of the IPPS wage index. For IPPS wage index purposes, for hospitals that were located in urban CBSAs in FY 2014 but were designated as rural under these revised OMB labor market area delineations, we generally assigned them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (79 FR 49957 through 49960). To be consistent, we applied the same policy to hospitals paid under the OPPS but not under the IPPS so that such hospitals maintained the wage index of the CBSA in which they were physically located for FY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018.

In addition, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20362 through 20363), we proposed not to extend the imputed floor policy under the IPPS for FY 2019 and subsequent fiscal years, and in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41376 through 41380), we finalized this proposal. Similarly, in the CY 2019 OPPS/ASC proposed rule, we proposed not to extend the imputed floor policy under the OPPS beyond December 31, 2018 (the date the policy is set to expire). The comments we received on this proposal, along with our response, are summarized above. As discussed earlier, consistent with the FY 2019 IPPS/LTCH PPS final rule, in this CY 2019 OPPS/ASC final rule with comment period, we are finalizing our proposal not to extend the imputed floor policy under the OPPS beyond December 31, 2018.

For CMHCs, for CY 2019, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. As with OPPS hospitals and for the same reasons, for CMHCs previously located in urban CBSAs that were designated as rural under the revised OMB labor market area delineations in OMB Bulletin No. 13–01, we finalized a policy to maintain the urban wage index value of the CBSA in which they were physically located for CY 2014 for 3 calendar years (until December 31, 2017). Because this 3-year transition ended at the end of CY 2017, it was not applied beginning in CY 2018. We proposed that the wage index that would apply to CMHCs for CY 2019 would include the rural floor adjustment, but would not include the imputed floor adjustment because, as discussed above, we proposed to not extend the imputed floor policy beyond December 31, 2018. Also, we proposed that the wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

We did not receive any public comments on these proposals. Therefore, for the reasons discussed above and in the CY 2019 OPPS/ASC proposed rule (83 FR 37076), we are finalizing these proposals without modification.

Table 2 associated with the FY 2019 IPPS/LTCH PPS final rule (available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) identifies counties eligible for the out-migration adjustment and IPPS hospitals that will receive the adjustment for FY 2019. We are including the out-migration adjustment information from Table 2 associated with the FY 2019 IPPS/LTCH PPS final rule as Addendum L to this final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2019 OPPS. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At this link, readers will find a link to the final FY 2019 IPPS wage index tables and Addendum L.

D. Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, CMS uses overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. MACs cannot calculate a CCR for some hospitals because there is no cost report available. For these hospitals, CMS uses the statewide average default CCRs to determine the payments mentioned earlier until a hospital's MAC is able to calculate the hospital's actual CCR from its most recently submitted Medicare cost report. These hospitals include, but are not limited to, hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. CMS also uses the statewide average default CCRs to determine payments for hospitals that appear to have a biased CCR (that is, the CCR falls outside the predetermined ceiling threshold for a valid CCR) or for hospitals in which the most recent cost report reflects an all-

inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37076), we proposed to update the default ratios for CY 2019 using the most recent cost report data. We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For detail on our process for calculating the statewide average CCRs, we referred readers to the CY 2019 OPPS proposed rule Claims Accounting Narrative that is posted on the CMS website. Table 5 published in the proposed rule (83 FR 37076 through 37078) listed the proposed statewide average default CCRs for OPPS services furnished on or after January 1, 2019, based on proposed rule data.

We did not receive any public comments on our proposal to use statewide average default CCRs if a MAC cannot calculate a CCR for a hospital and to use these CCRs to adjust charges to costs on claims data for setting the final CY 2019 OPPS relative payment weights. Therefore, we are finalizing our proposal without modification.

Table 9 below lists the statewide average default CCRs for OPPS services furnished on or after January 1, 2019, based on final rule data.

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TABLE 9.—CY 2019 STATEWIDE AVERAGE CCRs

State	Urban/Rural	CY 2019 Default CCR	Previous Default CCR (CY 2018 OPPS Final Rule)
ALASKA	RURAL	0.655	0.659
ALASKA	URBAN	0.219	0.218
ALABAMA	RURAL	0.185	0.190
ALABAMA	URBAN	0.153	0.155
ARKANSAS	RURAL	0.194	0.186
ARKANSAS	URBAN	0.195	0.200
ARIZONA	RURAL	0.245	0.232
ARIZONA	URBAN	0.161	0.160
CALIFORNIA	RURAL	0.180	0.181
CALIFORNIA	URBAN	0.188	0.193
COLORADO	RURAL	0.344	0.346
COLORADO	URBAN	0.198	0.204
CONNECTICUT	RURAL	0.323	0.324
CONNECTICUT	URBAN	0.248	0.249
DISTRICT OF COLUMBIA	URBAN	0.268	0.279
DELAWARE	URBAN	0.266	0.295
FLORIDA	RURAL	0.169	0.158
FLORIDA	URBAN	0.134	0.138
GEORGIA	RURAL	0.225	0.222
GEORGIA	URBAN	0.195	0.198
HAWAII	RURAL	0.340	0.332
HAWAII	URBAN	0.320	0.322
IOWA	RURAL	0.285	0.296
IOWA	URBAN	0.240	0.254
IDAHO	RURAL	0.418	0.339
IDAHO	URBAN	0.344	0.369
ILLINOIS	RURAL	0.206	0.214
ILLINOIS	URBAN	0.211	0.208
INDIANA	RURAL	0.250	0.299
INDIANA	URBAN	0.209	0.213
KANSAS	RURAL	0.258	0.264

State	Urban/Rural	CY 2019 Default CCR	Previous Default CCR (CY 2018 OPPS Final Rule)
KANSAS	URBAN	0.187	0.199
KENTUCKY	RURAL	0.175	0.184
KENTUCKY	URBAN	0.189	0.187
LOUISIANA	RURAL	0.212	0.212
LOUISIANA	URBAN	0.191	0.195
MASSACHUSETTS	RURAL	0.322	0.322
MASSACHUSETTS	URBAN	0.336	0.348
MAINE	RURAL	0.395	0.419
MAINE	URBAN	0.373	0.422
MARYLAND	RURAL	0.253	0.258
MARYLAND	URBAN	0.226	0.227
MICHIGAN	RURAL	0.297	0.302
MICHIGAN	URBAN	0.312	0.318
MINNESOTA	RURAL	0.364	0.379
MINNESOTA	URBAN	0.306	0.302
MISSOURI	RURAL	0.213	0.220
MISSOURI	URBAN	0.244	0.240
MISSISSIPPI	RURAL	0.209	0.213
MISSISSIPPI	URBAN	0.160	0.160
MONTANA	RURAL	0.476	0.486
MONTANA	URBAN	0.334	0.350
NORTH CAROLINA	RURAL	0.200	0.206
NORTH CAROLINA	URBAN	0.211	0.212
NORTH DAKOTA	RURAL	0.326	0.366
NORTH DAKOTA	URBAN	0.375	0.369
NEBRASKA	RURAL	0.293	0.313
NEBRASKA	URBAN	0.238	0.233
NEW HAMPSHIRE	RURAL	0.309	0.307
NEW HAMPSHIRE	URBAN	0.259	0.255
NEW JERSEY	URBAN	0.198	0.200
NEW MEXICO	RURAL	0.205	0.224
NEW MEXICO	URBAN	0.274	0.284
NEVADA	RURAL	0.163	0.175
NEVADA	URBAN	0.125	0.114
NEW YORK	RURAL	0.303	0.299
NEW YORK	URBAN	0.268	0.303

State	Urban/Rural	CY 2019 Default CCR	Previous Default CCR (CY 2018 OPPS Final Rule)
OHIO	RURAL	0.268	0.280
OHIO	URBAN	0.250	0.203
OKLAHOMA	RURAL	0.213	0.215
OKLAHOMA	URBAN	0.172	0.169
OREGON	RURAL	0.267	0.290
OREGON	URBAN	0.326	0.336
PENNSYLVANIA	RURAL	0.262	0.267
PENNSYLVANIA	URBAN	0.177	0.173
PUERTO RICO	URBAN	0.555	0.577
RHODE ISLAND	URBAN	0.277	0.276
SOUTH CAROLINA	RURAL	0.167	0.170
SOUTH CAROLINA	URBAN	0.184	0.191
SOUTH DAKOTA	RURAL	0.346	0.391
SOUTH DAKOTA	URBAN	0.237	0.242
TENNESSEE	RURAL	0.169	0.173
TENNESSEE	URBAN	0.179	0.174
TEXAS	RURAL	0.210	0.205
TEXAS	URBAN	0.167	0.168
UTAH	RURAL	0.298	0.391
UTAH	URBAN	0.318	0.304
VIRGINIA	RURAL	0.183	0.177
VIRGINIA	URBAN	0.210	0.215
VERMONT	RURAL	0.414	0.393
VERMONT	URBAN	0.397	0.378
WASHINGTON	RURAL	0.261	0.256
WASHINGTON	URBAN	0.326	0.323
WISCONSIN	RURAL	0.348	0.348
WISCONSIN	URBAN	0.314	0.308
WEST VIRGINIA	RURAL	0.257	0.253
WEST VIRGINIA	URBAN	0.276	0.297
WYOMING	RURAL	0.401	0.407
WYOMING	URBAN	0.325	0.327

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E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2019

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis

showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised § 419.43(g) of the regulations to clarify that essential access community hospitals (EACHs) also are eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Pub. L. 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2018. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37078), for the CY 2019 OPPS, we proposed to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. We invited public comment on our proposal.

In addition, we proposed to maintain this 7.1 percent payment adjustment for the years after CY 2019 until we identify data in the future that would support a change to this payment adjustment. We invited public comments on our proposal.

Comment: Several commenters supported the proposal to continue the 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. A few commenters explicitly supported the part of the proposal that would allow the adjustment to continue after CY 2019 until CMS identifies data that would cause CMS to reassess the adjustment. These commenters approved of having more certainty about whether the rural SCH adjustment would be in effect on an ongoing basis, because it would help hospitals covered by the adjustment improve their budget forecasting based on expected revenues.

Response: We appreciate the commenters' support.

Comment: One commenter suggested that CMS further examine whether the payment adjustment for rural SCHs, including EACHs, should continue to be 7.1 percent. The commenter noted the rate of the payment adjustment was based on data analyses that are more than 10 years old.

Response: While the data for the initial analyses are more than 10 years old, we periodically review the calculations used to generate the rural SCHs and EACHs adjustment. For any given year, the level of increased costs experienced by rural SCH and EACH may be higher or lower than the current 7.1 percent adjustment. Since being established in CY 2008, we believe the payment increase of 7.1 percent has continued to reasonably reflect the increased costs that rural SCHs and EACHs face when providing outpatient hospital services based on regression analyses performed on the claims data.

Comment: Some commenters requested that CMS expand the payment adjustment for rural SCHs and EACHs to additional types of hospitals. One commenter requested that the payment adjustment apply to include urban SCHs because, according to the commenter, urban SCHs care for patient populations similar to rural SCHs and EACHs, face similar financial challenges to rural SCHs and EACHs, and act as safety net providers for rural areas despite their designation as urban providers. Another commenter requested that the payment adjustment also apply to Medicare-dependent hospitals (MDHs) because, according to the commenter, these hospitals face similar financial challenges to rural SCHs and EACHs, and MDHs play a similar safety net role to rural SCHs and EACHs, especially for Medicare. One commenter requested that payment rates for OPPS services for all rural hospitals be increased to reduce financial vulnerability for rural hospitals related to the high share of Medicare and Medicaid beneficiaries they serve.

Response: We thank the commenters for their comments. However, the analysis we did to compare costs of urban providers to those of rural providers did not support an add-on adjustment for providers other than rural SCHs and EACHs, and our follow-up analyses performed in recent years have not shown differences in costs for all services for any of the additional types of providers mentioned by the commenters. Accordingly, we do not believe we currently have a basis to expand the payment adjustment to any other providers other than rural SCHs and EACHs.

After consideration of the public comments we received, we are implementing our proposals, without modification, to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. In addition, we will maintain this 7.1 percent payment adjustment for the years after CY 2019 until our data support a change to this payment adjustment.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2019

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,''

and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR for purposes of the cancer hospital payment adjustment was 0.89. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266).

2. Policy for CY 2019

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying 42 CFR 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37079), for CY 2019, we proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. We invited public comment on our proposal.

We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2019. To calculate the proposed CY 2019 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of the proposed rule and this final rule with comment period, used to estimate costs for the CY 2019 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2017 claims data that we used to model the impact of the proposed CY 2019 APC relative payment weights (3,676 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2019 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2017. We then removed the cost report data of the 43 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 18 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,615 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 89 percent of reasonable cost (weighted average PCR of 0.89). Therefore, after applying the

1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.88 for each cancer hospital.

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposed cancer hospital payment adjustment methodology without modification. For this final rule with comment period, we are using the most recent cost report data through June 30, 2018 to update the adjustment. This update yields a target PCR of 0.89. We limited the dataset to the hospitals with CY 2017 claims data that we used to model the impact of the CY 2019 APC relative payment weights (3,696 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2019 OPPS. The cost report data for the hospitals in the dataset were from cost report periods with fiscal year ends ranging from 2010 to 2018. We then removed the cost report data of the 46 hospitals located in Puerto Rico from our dataset because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 22 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to an analytic file of 3,628 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated a target PCR of 0.89. Therefore, after applying the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act, we are finalizing that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.88 for each cancer hospital. Table 10 below shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2019, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2019 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2019 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

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TABLE 10.—ESTIMATED CY 2019 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2019 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	37.1%
050660	USC Norris Cancer Hospital	13.4%
100079	Sylvester Comprehensive Cancer Center	21.0%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3%
220162	Dana-Farber Cancer Institute	43.7%
330154	Memorial Sloan-Kettering Cancer Center	46.4%
330354	Roswell Park Cancer Institute	16.2%
360242	James Cancer Hospital & Solove Research Institute	22.6%
390196	Fox Chase Cancer Center	8.4%
450076	M.D. Anderson Cancer Center	53.6%
500138	Seattle Cancer Care Alliance	54.3%

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G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2018, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $4,150 (the fixed-dollar amount threshold) (82 FR 59267 through 59268). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2017 OPPS payments, using CY 2017 claims available for the CY 2019 OPPS/ASC proposed rule (83 FR 37080 through 37081), was approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2017, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this CY 2019 OPPS final rule with comment period, we estimate that we paid approximately 1.12 percent of the total aggregated OPPS payments in outliers for CY 2017.

For the CY 2019 OPPS/ASC proposed rule, using CY 2017 claims data and CY 2018 payment rates, we estimate that the aggregate outlier payments for CY 2018 would be approximately 1.02 percent of the total CY 2018 OPPS payments. We provided estimated CY 2019 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation for CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37080 through 37081), for CY 2019, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of the CY 2019 OPPS/ASC proposed rule (83 FR 37134 through 37136), we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of the proposed rule and this final rule with comment period.

To ensure that the estimated CY 2019 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $4,600.

We calculated the proposed fixed-dollar threshold of $4,600 using the standard methodology most recently used for CY 2018 (82 FR 59267 through 59268). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2018 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2019 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2017 claims using the same inflation factor of 1.085868 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20581). We used an inflation factor of 1.04205 to estimate CY 2018 charges from the CY 2017 charges reported on CY 2017 claims. The methodology for determining this charge inflation factor is discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 20581). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2019 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2019 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2019, we proposed to apply an adjustment factor of 0.987842 to the CCRs that were in the April 2018 OPSF to trend them forward from CY 2018 to CY 2019. The methodology for calculating the proposed adjustment is discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20582).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2018 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.987842 to approximate CY 2019 CCRs) to charges on CY 2017 claims that were adjusted (using the proposed charge inflation factor of 1.085868 to approximate CY 2019 charges). We simulated aggregated CY 2019 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold

constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2019 OPPS payments. We estimated that a proposed fixed-dollar threshold of $4,600, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, as we proposed, we are continuing the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we referred readers to section XIII. of this final rule with comment period.

Comment: One commenter expressed concern that, due to the increase in the proposed fixed-dollar threshold to $4,600 relative to the previous CY 2018 fixed-dollar outlier threshold of $4,150, the drastic reduction in outlier payments would have an adverse effect on access to services for Medicare beneficiaries. Therefore, the commenter requested that the threshold be transitioned over a 3-year period.

Response: As indicated earlier, we introduced a fixed-dollar threshold in order to better target outlier payments to those high-cost and complex procedures where a very costly service could present a hospital with significant financial loss. We maintain the target outlier percentage of 1.0 percent of estimated aggregate total payment under the OPPS and have a fixed-dollar threshold so that OPPS outlier payments are made only when the hospital would experience a significant loss for furnishing a particular service. The methodology we use to calculate the fixed-dollar threshold for the prospective payment year factors is based on several data inputs that may change from prior payment years. For instance, updated hospital CCR data and changes to the OPPS payment methodology influence projected outlier payments in the prospective year.

We do not believe that it is appropriate to transition towards implementation of the CY 2019 OPPS fixed-dollar outlier threshold in the manner described by the commenter. The fixed-dollar outlier threshold is specifically developed in order to best estimate aggregate outlier payments of 1 percent of the OPPS. In addition, transitioning in this suggested manner would remove the consideration of updated data, which is critical in best estimating the fixed-dollar threshold that would result in total OPPS outliers being 1 percent of aggregate OPPS payments. Finally, we note that the increase in the fixed-dollar outlier threshold does not necessarily result in a decrease in aggregate OPPS outlier payments. Rather, it ensures that the aggregate pool remains at 1 percent and that outlier payments are directed towards the high cost and complex procedures associated with potential financial risk.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2019.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2019, we are applying the overall CCRs from the October 2018 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.9813 to approximate CY 2019 CCRs) to charges on CY 2017 claims that were adjusted using a charge inflation factor of 1.0434 to approximate CY 2019 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar thresholds for the FY 2019 IPPS/LTCH PPS final rule (83 FR 41722). We simulated aggregated CY 2019 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payment equaled 1.0 percent of aggregated estimated total CY 2019 OPPS payments. We estimate that a fixed-dollar threshold of $4,825 combined with the multiple threshold of 1.75 times the APC payment rate, will allocated the 1.0 percent of aggregated total OPPS payments to outlier payments.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under PAC 5853, exceeds 3.40 times the payment rate the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2019 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) was calculated by multiplying the CY 2019 scaled weight for the APC by the CY 2019 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage

points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIII. of this final rule with comment period.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37082), we demonstrated the steps to determine the APC payments that will be made in a calendar year under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to the proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We noted that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

We did not receive any public comments specific to the steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2019. Therefore, we are finalizing use of the steps in the methodology specified below, as we proposed, to demonstrate the calculation of the final CY 2019 OPPS payments using the same parameters.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.980 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements in order to receive the full CY 2019 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, under the CY 2019 OPPS policy for continuing to use the OMB labor market area delineations based on the 2010 Decennial Census data for the wage indexes used under the IPPS, a hold harmless policy for the wage index may apply, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2019 under the IPPS, reclassifications through the Metropolitan Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, reclassifications under section 1886(d)(8)(E) of the Act, as defined in § 412.103 of the regulations, and hospitals designated as urban under section 601(g) of Public Law 98–21. For further discussion of the changes to the FY 2019 IPPS wage indexes, as applied to the CY 2019 OPPS, we refer readers to section II.C. of this final rule with comment period. We are continuing to apply a wage index floor of 1.00 to frontier States, in accordance with section 10324 of the Affordable Care Act of 2010.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the FY 2019 IPPS, which are listed in Table 2 associated with the FY 2019 IPPS/LTCH PPS final rule available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2019 IPPS Final Rule Home Page'' and select ''FY 2019 Final Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a *is the labor-related portion of the national unadjusted payment rate (wage adjusted).*

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not

attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined above. For purposes of this example, we used a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The CY 2019 full national unadjusted payment rate for APC 5071 is approximately $579.34. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is approximately $567.75. This reduced rate is calculated by multiplying the reporting ratio of 0.980 by the full unadjusted payment rate for APC 5071.

The FY 2019 wage index for a provider located in CBSA 35614 in New York is 1.2853. The labor-related portion of the full national unadjusted payment is approximately $446.77 (.60 * $579.34 * 1.2853). The labor-related portion of the reduced national unadjusted payment is approximately $437.84 (.60 * 567.75 * 1.2853). The nonlabor-related portion of the full national unadjusted payment is approximately $231.74 (.40 * $579.34). The nonlabor-related portion of the reduced national unadjusted payment is approximately $227.10 (.40 * $567.75). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $678.51 ($446.77 + $231.74). The sum of the portions of the reduced national adjusted payment is approximately $664.94 ($437.84 + $227.10).

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in calendar years thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

In the CY 2019 OPPS/ASC proposed rule (83 FR 37083), for CY 2019, we proposed to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2019 were included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

As discussed in section XIII.E. of the proposed rule and this final rule with comment period, for CY 2019, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest

coinsurance percentage of the codes comprising the new APC.

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

Comment: One commenter supported the beneficiary copayment limit that may be collected for certain drugs to the amount of the inpatient hospital deductible for that year.

Response: We appreciate the commenter's support. We note that section 1833(t)(8)(C)(i) of the Act requires us to limit the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $115.87 is approximately 20 percent of the full national unadjusted payment rate of $579.34. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.980.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2019, are shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2019 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

CPT codes are established by the American Medical Association (AMA) and the Level II HCPCS codes are established by CMS. These codes are updated and changed throughout the year. CPT and HCPCS code changes that affect the OPPS are published both through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). CMS releases new Level II HCPCS codes to the public

or recognizes the release of new CPT codes by the AMA and makes these codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new CPT and Level II HCPCS codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that may more accurately describe items or services furnished and provides payment or more accurate payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on these new codes and finalize our proposals related to these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment, while other payment status indicators do not. Section XI. of this final rule with comment period discusses the various status indicators used under the OPPS.

In Table 11 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

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TABLE 11.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) CPT Codes, Category III CPT codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period
January 1, 2019	Category I and III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period

1. Treatment of New HCPCS Codes That Were Effective April 1, 2018 for Which We Solicited Public Comments in the CY 2019 OPPS/ASC Proposed Rule

Through the April 2018 OPPS quarterly update CR (Transmittal 4005, Change Request 10515, dated March 20, 2018), we made effective nine new Level II HCPCS codes for separate payment under the OPPS. In the CY 2019 OPPS/ASC proposed rule (83 FR 37085), we solicited public comments on the proposed APC and status indicator assignments for these Level II HCPCS codes, which were listed in Table 8 of the proposed rule.

We received some public comments related to HCPCS code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s)), which we address in section III.D.16. of this final rule with comment period. With the exception of HCPCS code C9749, we did not receive any public comments on the proposed OPPS APC and status indicator assignments for the new Level II HCPCS codes implemented in April 2018. Therefore, we are finalizing the proposed APC and status indicator assignments for these codes, as indicated in Table 12 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2019. Their replacement codes are listed in Table 12. The final payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum D1 to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 12.—NEW LEVEL II HCPCS CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462
C9463	J0185	Injection, aprepitant, 1 mg	G	9463
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464
C9465	J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	G	9465
C9466	J0517	Injection, benralizumab, 1 mg	G	9466
C9467	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467
C9468	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468
C9469*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469
C9749	C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J1	5164

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018. HCPCS code Q9993 was deleted December 31, 2018, and replaced with HCPCS code J3304 effective January 1, 2019.

In addition, there were several new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M-codes) and Proprietary Laboratory Analyses (PLA) codes (U-codes) that were effective April 1, 2018, but were too late to include in the April 2018 OPPS Update. Because these codes were released on the American Medical Association's (AMA) CPT website in February 2018, they were too late for us to include in the April 2018 OPPS Update CR and in the April 2018 Integrated Outpatient Code Editor (IOCE) and, consequently, were included in the July 2018 OPPS Update with an effective date of April 1, 2018. These CPT codes were listed in Table 9 of the CY 2019 OPPS/ASC proposed rule (83 FR 37086). In the proposed rule, we solicited public comments on the proposed APC and status indicator assignments for these CPT codes. The proposed payment rates for these codes, where applicable, were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: One commenter stated that the test described by CPT code 0037U (Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden) specifically, FoundationOne CDx™, is a human DNA tumor mutation profiling test that is covered by Medicare and has been designated as an Advanced Diagnostic Laboratory Test (ADLT) under the Clinical Laboratory Fee Schedule (CLFS). The commenter supported the proposed OPPS status indicator assignment of ''A'' (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS) for CPT code 0037U.

Response: We thank the commenter for the feedback. CPT code 0037U,

which is covered by Medicare, met the criteria for classification as a new ADLT and received its ADLT status in May 2018. Under the OPPS, codes that receive ADLT status under section 1834A(d)(5)(A) of the Act are assigned to status indicator ''A''. Therefore, we are finalizing the OPPS status indicator ''A'' for CPT code 0037U as proposed.

After consideration of the public comment we received, we are finalizing the proposed status indicator assignments for the new MAAA and PLA CPT codes effective April 1, 2018. The final status indicator assignments for the CPT codes are listed in Table 13 below. The status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2019) to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 13.—NEW CPT MAAA AND PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE APRIL 1, 2018

CY 2018 HCPCS Code	CY 2018 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma	A	N/A
0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma	A	N/A
0035U	Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative	Q4	N/A
0036U	Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses	A	N/A
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden	A	N/A
0038U	Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative	Q4	N/A
0039U	Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity	Q4	N/A
0040U	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative	A	N/A
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM	Q4	N/A

CY 2018 HCPCS Code	CY 2018 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG	Q4	N/A
0043U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM	Q4	N/A
0044U	Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG	Q4	N/A

2. Treatment of New HCPCS Codes That Were Effective July 1, 2018 for Which We Solicited Public Comments in the CY 2019 OPPS/ASC Proposed Rule

Through the July 2018 OPPS quarterly update CR (Transmittal 4075, Change Request 1078, dated June 15, 2018), we made 4 new Category III CPT codes and 10 Level II HCPCS codes effective July 1, 2018 (14 codes total), and assigned them to appropriate interim OPPS status indicators and APCs. As listed in Table 10 of the CY 2019 OPPS/ASC proposed rule (83 FR 37086 through 37087), 13 of the 14 HCPCS codes are separately payable under the OPPS while 1 HCPCS code is not. Specifically, HCPCS code Q9994 is assigned to status indicator ''E1'' to indicate that the item is not payable by Medicare. In addition, we note that HCPCS code C9469 was deleted June 30, 2018, and replaced with HCPCS code Q9993 effective July 1, 2018. Because HCPCS code Q9993 describes the same drug as HCPCS code C9469, we proposed to continue the drug's pass-through payment status and to assign HCPCS code Q9993 to the same APC and status indicators as its predecessor HCPCS code C9469, as shown in Table 10 of the proposed rule.

In the CY 2019 OPPS/ASC proposed rule, we solicited public comments on the proposed APC and status indicator assignments for CY 2019 for the CPT and Level II HCPCS codes implemented on July 1, 2018, all of which were listed in Table 10 of the proposed rule. The proposed payment rates and status indicators for these codes, where applicable, were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

We did not receive any public comments on the proposed APC and status indicator assignments for the new Category III CPT codes and Level II HCPCS codes implemented in July 2018. Therefore, we are finalizing the proposed APC and status indicator assignments for these codes, as indicated in Table 14 below. We note that several of the HCPCS C and Q-codes have been replaced with HCPCS J-codes effective January 1, 2019. Their replacement codes are listed in Table 14 below. The final payment rates for these codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2019) to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 14.—NEW HCPCS CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
C9030	J9057	Injection, copanlisib, 1 mg	G	9030
C9031	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	G	9067
C9032	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	G	9070
Q5105	Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239
Q9993*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469
Q9994	Q9994	In-line cartridge containing digestive enzyme(s) for enteral feeding, each	E1	N/A
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257
0505T	0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	J1	5193

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0506T	0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	Q1	5733
0507T	0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	Q1	5733
0508T	0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	S	5522

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), effective July 1, 2018. HCPCS code Q9993 was deleted December 31, 2018, and replaced with HCPCS code J3304, effective January 1, 2019.

In addition, there are several new PLA codes (U-codes) that were effective July 1, 2018, but were too late to include in the July 2018 OPPS Update. Consequently, the codes were included in the October 2018 OPPS Update with an effective date of July 1, 2018. The CPT codes were listed in Table 11 of the CY 2019 OPPS/ASC proposed rule along with the proposed APC and status indicator assignments for these CPT codes. In the CY 2019 OPPS/ASC proposed rule (83 FR 37087), we solicited public comments on the proposed APC and status indicator assignments for the CPT codes. The proposed payment rates for these codes, where applicable, were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

We did not receive any public comments on the proposed status indicator assignments for the PLA codes effective July 1, 2018. Therefore, we are finalizing the proposed status indicator assignments for these codes, as indicated in Table 15 below. We note that the status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2019) to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 15.—NEW CPT PROPRIETARY LABORATORY ANALYSES (PLA) CODES EFFECTIVE JULY 1, 2018

CY 2018 HCPCS Code	CY 2018 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score	A	N/A
0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative	A	N/A
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score	A	N/A
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)	A	N/A
0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative	A	N/A
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements	A	N/A
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service	Q4	N/A

CY 2018 HCPCS Code	CY 2018 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation	Q4	N/A
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade	A	N/A
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service	Q4	N/A
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma	A	N/A
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)	A	N/A
0057U	Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank	A	N/A
0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative	Q4	N/A
0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative	Q4	N/A

CY 2018 HCPCS Code	CY 2018 Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood	A	N/A
0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis	Q4	N/A

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3. Process for New Level II HCPCS Codes That Are Effective October 1, 2018 or Will Be Effective on January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective October 1 and January 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year, as displayed in Table 11 of this final rule with comment period. These codes are released to the public through the October and January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes). For CY 2019, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the interim status indicator and APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37088), we proposed to continue this process for CY 2019. Specifically, for CY 2019, we proposed to include in Addendum B to the CY 2019 OPPS/ASC final rule with comment period the following new HCPCS codes:

- New Level II HCPCS codes effective October 1, 2018, that would be incorporated in the October 2018 OPPS quarterly update CR; and
- New Level II HCPCS codes effective January 1, 2019, that would be incorporated in the January 2019 OPPS quarterly update CR.

As stated above, the October 1, 2018 and January 1, 2019 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned these codes an interim OPPS payment status for CY 2019. We are inviting public comments on the interim status indicator and APC assignments for these codes, if applicable, that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

4. Treatment of New and Revised CY 2019 Category I and III CPT Codes That Will Be Effective January 1, 2019 for Which We Solicited Public Comments in the CY 2019 OPPS/ASC Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the annual proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2019 OPPS update, we received the CY 2019 CPT codes from AMA in time for inclusion in the CY 2019 OPPS/ASC proposed rule. The new, revised, and deleted CY 2019 Category I and III CPT codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We noted in the proposed rule that the new and revised codes are assigned to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing

code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC and status indicator assignments.

Further, we reminded readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2019 CPT codes in Addendum O to the proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on the proposed APCs and status indicator assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2019 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the proposed rule. We noted that the final CPT code numbers will be included in this CY 2019 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned to comment indicator ''NP''.

In summary, in the CY 2019 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2019 status indicator and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2019. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2019 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2019 OPPS/ASC proposed rule. We have responded to those public comments in sections II.A.2.b. (Comprehensive APCs), III.D. (OPPS APC-Specific Policies), IV.B. (Device-Intensive Procedures) and XII. (Updates to the ASC Payment System) of this CY 2019 OPPS/ASC final rule with comment period.

The final status indicators, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2019 can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2019) to this final rule with comment period (which is available via the internet on the CMS website).

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I and Level II HCPCS codes to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2019 OPPS/ASC proposed rule (83 FR 37089), for CY 2019, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the HOP Panel recommendations for specific services for the CY 2019 OPPS update are discussed in the relevant specific sections throughout this CY 2019 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under

the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In the CY 2019 OPPS/ASC proposed rule (83 FR 37089), for CY 2019, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2019 OPPS update, in the CY 2019 OPPS/ASC proposed rule, we identified the APCs with violations of the 2 times rule. Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the proposed rule. We noted that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2019 OPPS/ASC proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2019 included in the proposed rule were related to changes in costs of services that were observed in the CY 2017 claims data newly available for CY 2019 ratesetting. Addendum B to the CY 2019 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2018 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*).

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2019 in the CY 2019 OPPS/ASC proposed rule, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2017 claims data available for the CY 2019 proposed rule, we found 16 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2019, and found that all of the 16 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2017 claims data available for the proposed rule. We did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have a similar geometric mean costs and do not create a 2 time rule violation. Therefore, we only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 12 of the proposed rule listed the 16 APCs that we proposed to make an exception for under the 2 times rule for CY 2019 based on the criteria cited above and claims data submitted between January 1, 2017, and December 31, 2017, and processed on or before December 31, 2017. In the proposed rule, we stated that, for the final rule with comment period, we intend to use claims data for dates of service between January 1, 2017, and December 31, 2017, that were processed on or before June 30, 2018, and updated CCRs, if available.

Based on the updated final rule CY 2017 claims data used for this CY 2019 final rule with comment period, we were able to remedy 1 APC violation out of the 16 APCs that appeared in Table 12 of the CY 2019 OPPS/ASC proposed rule. Specifically, APC 5735 (Level 5 Minor Procedures) no longer met the criteria for exception to the 2 times rule in this final rule with comment period. In addition, based on our analysis of the final rule claims data, we found a total of 17 APCs with violations of the 2 times rule. Of these 17 total APCs, 15 were identified in the proposed rule and 2 are newly identified APCs. Specifically, we found the following 15 APCs that were identified for the proposed rule that continued to have violations of the 2 times rule for this final rule with comment period:

- APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage);
- APC 5113 (Level 3 Musculoskeletal Procedures);
- APC 5521 (Level 1 Imaging without Contrast);
- APC 5522 (Level 2 Imaging without Contrast);
- APC 5523 (Level 3 Imaging without Contrast);
- APC 5571 (Level 1 Imaging with Contrast);
- APC 5612 (Level 2 Therapeutic Radiation Treatment Preparation);
- APC 5691 (Level 1 Drug Administration);
- APC 5692 (Level 2 Drug Administration);
- APC 5721 (Level 1 Diagnostic Tests and Related Services);
- APC 5724 (Level 4 Diagnostic Tests and Related Services);
- APC 5731 (Level 1 Minor Procedures);
- APC 5732 (Level 2 Minor Procedures);
- APC 5822 (Level 2 Health and Behavior Services); and
- APC 5823 (Level 3 Health and Behavior Services).

In addition, we found that the following two additional APCs violated the 2 times rule using the final rule with comment period claims data:

- APC 5193 (Level 3 Endovascular Procedures); and
- APC 5524 (Level 4 Imaging without Contrast).

After considering the public comments we received on proposed APC assignments and our analysis of the CY 2017 costs from hospital claims and cost report data available for this CY 2019 final rule with comment period, we are finalizing our proposals, with some modifications. Specifically, we are

finalizing our proposal to except 15 of the 16 proposed APCs from the 2 times rule for CY 2019 and also excepting 2 additional APCs (APCs 5193 and 5524). As noted above, we were able to remedy one of the proposed rule 2 time rule violations in this final rule with comment period (APC 5735).

Table 16 below lists the 17 APCs that we are excepting from the 2 times rule for CY 2019 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2017 and December 31, 2017, that were processed on or before June 30, 2018, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *http://www.cms.gov*.

TABLE 16.—APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2019

CY 2019 APC	CY 2019 APC Title
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5193	Level 3 Endovascular Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level1 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2018, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase. We

believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. (We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.)

We note that, in a budget neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2019, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to the CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website). The final payment rates for these New Technology APCs are included in Addendum A to the CY 2019 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Procedures

Procedures that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new procedure so that it can be assigned to an appropriate clinical APC. Some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. For these low-volume procedures, we are concerned that the methodology we use to estimate the cost of a procedure under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the procedure.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a procedure to a new technology APC allows us to gather claims data to price the procedure and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we believe that it is appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs. We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology procedures in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we believe that it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order mitigate the wide payment fluctuations that can occur for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we believe that it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we define as fewer than 100 claims annually. We consider procedures with fewer than 100 claims annually as low-volume procedures because there is a higher probability that the payment data for a procedure may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. For these low-volume procedures, we are concerned that the methodology we use to estimate the cost of a procedure under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the procedure. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we believe that using the median or arithmetic mean rather than the geometric mean (which

''trims'' the costs of certain claims out) may be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We believe that having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37091 through 37092), we proposed that, in each of our annual rulemakings, we would seek public comments on which statistical methodology should be used for each low-volume New Technology APC. In the preamble of each annual rulemaking, we stated that we will present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we will use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identify the most appropriate payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37091 through 37092), for CY 2019, we proposed to establish a different payment methodology for services assigned to New Technology APCs with fewer than 100 claims using our equitable adjustment authority under section 1833(t)(2)(E) of the Act. Under this proposal, we proposed to use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC. The goal of such a policy is to promote transparency and stability in the payment rates for these low-volume new technology procedures and to mitigate wide variation from year to year for such services. We also proposed to use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service, present the result of each statistical methodology in our annual rulemaking, and solicit public comment on which methodology should be used to establish the payment rate. We stated that the geometric mean may not be representative of the actual cost of a service when fewer than 100 claims are present because the payment amounts for the claims may not be distributed normally. We stated that, under this proposal, we would have the option to use the median payment amount or the arithmetic mean to assign a more representative payment for the service. Once we identify the payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

Comment: One commenter requested that CMS expand the proposal to cover all low-volume procedures with fewer than 100 claims annually in the OPPS rather than only those procedures assigned to New Technology APCs. The commenter noted the issues cited for establishing the low-volume policy, including data not having a normal statistical distribution, excessive influence of outliers, and the quality of claims data affect all low-volume procedures, and not just those procedure assigned to a New Technology APC.

Response: We disagree with the commenter's request. The fact that a procedure has been assigned to a clinical APC means we have some idea of the resources used for a low-volume procedure and what the cost of the procedure should be. Concerns over the appropriate APC assignment for an individual procedure may be addressed on a case-by-case basis through our annual rulemaking. We remind commenters that they can submit public comments on the appropriate APC assignment for a particular code during that process. We believe reviewing each procedure assigned to a clinical APC annually to determine if the arithmetic mean, geometric mean, or median of the claims data should be used to determine the procedure cost is both unnecessary and operationally infeasible. The low-volume policy instead is intended only for those procedures assigned to New Technology APCs with such limited claims data that we are not able to assign them to clinical APCs and need as much available data to determine the payment rate for a procedure.

Comment: One commenter asked that CMS use the equitable adjustment authority under section 1833(t)(2)(E) of the Act in other instances not covered by the proposed low-volume policy where a procedure that has recently been introduced to the outpatient setting has inconsistent payment data due to small number of claims.

Response: We retain the ability to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act when we determine that it is needed.

Comment: Several commenters supported the proposal to use up to 4 years of claims data and to have flexibility to use the geometric mean, arithmetic mean, or median of claims data to establish a payment rate for low-volume procedures assigned to a New Technology APC.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposed policy to establish payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to New Technology APCs, without modification. We may use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC. We will use the geometric mean, the median, or the arithmetic mean to calculate the cost of furnishing the applicable service, present the result of each statistical methodology in our annual rulemaking, and solicit public comment on which methodology should be used to establish the payment rate. Once we identify the payment rate for a service, we would assign the service to the New Technology APC with the cost band that includes its payment rate.

3. Procedures Assigned to New Technology APC Groups for CY 2019

As we explained in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a

different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2019, in the CY 2019 OPPS/ASC proposed rule (83 FR 37092), we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902).

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we proposed to continue to assign to standard APCs, and one that we proposed to reassign to a different New Technology APC for CY 2019. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

As shown in Table 13 of the CY 2019 OPPS/ASC proposed rule, and as listed in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to continue to assign the procedures described by CPT codes 0071T and 0072T to APC 5414 (Level 4 Gynecologic Procedures), with a proposed payment rate of approximately $2,410 for CY 2019. We also proposed to continue to assign the APC to status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC) to indicate that payment for all covered Part B services reported on the claim are packaged with the payment for the primary ''J1'' service for the claim, except for services assigned to OPPS status indicator ''F'', ''G'', ''H'', ''L'', and ''U''; ambulance services; diagnostic and screening mammography; all preventive services; and certain Part B inpatient services. In addition, we proposed to continue to assign the services described by HCPCS code C9734 (Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance) to APC 5115 (Level 5 Musculoskeletal Procedures), with a proposed payment rate of approximately $10,936 for CY 2019. We also proposed to continue to assign HCPCS code C9734 to status indicator ''J1''.

For procedures described by CPT code 0398T, we have only identified one paid claim for a procedure in CY 2016 and two paid claims in CY 2017, for a total of three paid claims. We note that the procedures described by CPT code 0398T were first assigned to a New Technology APC in CY 2016. Accordingly, there are only 2 years of claims data available for the OPPS ratesetting purposes. The payment amounts for the claims varied widely, with a cost of $29,254 for the sole CY 2016 claim and a geometric mean cost of $4,647 for the two CY 2017 claims. In the proposed rule, we expressed concerned that the reported geometric mean cost for CY 2017, which we would normally use to determine the proposed payment rate for the procedures described by CPT code 0398T, was significantly lower than the reported cost of the claim received in CY 2016, as well as the payment rate for the procedures for CY 2017 ($9,750.50) and for CY 2018 ($17,500.50). In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources.

Therefore, as mentioned in section III.C.2. of the proposed rule, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more likely to be representative of the cost of the procedures described by CPT code 0398T, despite the low geometric mean costs for procedures described by CPT code 0398T available in the claims data used for the proposed rule. We stated that we continue to believe that this situation for the procedures described by CPT code 0398T is unique, given the very limited number of claims for the procedures and the high variability for the cost of the claims which makes it challenging to determine a reliable payment rate for the procedures.

Our analysis found that the arithmetic mean of the three claims is $12,849.11, the geometric mean of the three claims is $8,579.91 (compared to $4,646.56 for CY 2017), and the median of the claims is $4,676.77. Consistent with what we stated in section III.C.2. of the proposed rule, we presented the result of each statistical methodology in this preamble, and we sought public comments on which method should be used to establish payment for the procedures described by CPT code 0398T. We believe that the arithmetic mean is the most appropriate representative cost of the procedures described by CPT code 0398T, which gives consideration to the payment rates established for the procedures in CY 2017 and CY 2018, without any trimming. The arithmetic mean also gives consideration to the full range in cost for the three paid claims, which represent 2 years of claims data for the procedures. We proposed to estimate the proposed payment rate for the procedures described by CPT code 0398T by calculating the arithmetic mean of the three paid claims for the procedures in CY 2016 and CY 2017, and assigning the procedures described by CPT code 0398T to the New Technology APC that includes the estimated cost. Accordingly, we proposed to reassign the procedures described by CPT code 0398T from APC 1576 (New Technology—Level 39 ($15,001–$20,000)) to APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a proposed payment rate of $12,500.50 for CY 2019. We refer readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

Comment: Several commenters opposed the proposed reassignment of CPT code 0398T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)), which has a payment rate of $12,500.50. These commenters asked CMS to maintain the CY 2018 assignment of CPT code 0398T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)). The commenters believed the cost of the services described by CPT code 0398T is more than the proposed payment rate of $12,500.50, and reducing payment would discourage use of this new technology. One commenter, the developer of the procedure, stated that the reduced payment rate would be particularly problematic as it would take effect just as MACs are issuing local coverage determinations to allow the procedure to be covered more widely by Medicare. This commenter also believed the two claims from CY 2017 with a geometric mean cost of $4,647 had too low of a payment rate and submitted additional payment data to CMS to support that position.

Response: Since the proposed rule was issued, there have been several more claims for services described by CPT code 0398T that were paid in CY 2017. Currently, there are 11 paid claims for services described by CPT code 0398T for CY 2017, and these 11 claims have an estimated cost of between $4,186.51 and $5,153.28. We performed our low-volume new technology process for CPT code 0398T for all available claims from CY 2017 and included the one claim of $29,254 from CY 2016. The results of our analysis found that for claims billed with CPT code 0398T, the geometric mean cost was $5,360.99, the arithmetic mean cost was $6,654.68, and the median cost was $4,581.45.

We have concerns about using the claims data available for this final rule with comment period to set the payment rate for CPT code 0398T for CY 2019. The payment rate for CPT code 0398T for CY 2018 was $17,500.50, and in the CY 2019 proposed rule (83 FR 37093), we proposed a payment rate of $12,500.50. However for this final rule with comment period, the highest payment rate using the most recent available claims data and the newly adopted smoothing methodology for low-volume New Technology APCs is $6,750.50, which is the mid-point of New Technology APC 1531. New Technology APC 1531 is the cost band for the arithmetic mean cost of CPT code 0398T. A payment rate of $6,750.50 would be the result of a $10,750 reduction in the payment rate in a period of just 1 year, or a payment rate reduction of over 60 percent. In addition, this payment reduction would be based on a total of 14 claims that have been billed for CPT code 0398T since we first received claims for this procedure in CY 2016. We believe that it is important to mitigate significant payment differences, especially payment differences that result in shifts of over $10,000 in a single year, while also basing payment rates on available costs information and claims data. We are concerned that these large changes in payment could potentially create an access to care issue for services described by CPT code 0398T; especially, when the procedure is starting to receive local coverage determinations from MACs allowing more Medicare beneficiaries to use the procedure. While the proposed payment rate of $12,500.50 is also a decrease from the current payment rate, we believe that it would be appropriate to finalize the proposed rate to mitigate a much sharper decline in payment from one year to the next.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Accordingly, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the proposed rate for this procedure, despite the lower geometric mean, arithmetic mean, and median costs calculated from the claims data used for this final rule with comment period. As stated earlier, we believe that this situation is unique, given the large reduction in payment this would represent for CPT code 0398T and the very limited number of claims reported for the procedure. Therefore, for CY 2019, we are reassigning CPT code 0398T from APC 1576 to APC 1575 (New Technology—Level 38 ($10,001–$15,000)). This APC assignment will establish a payment rate for CPT code 0398T of $12,500.50, which was the proposed payment rate for the procedure in the CY 2019 OPPS/ASC proposed rule. As we do each year, we acquire claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures like CPT code 0398T as they transition into mainstream medical practice (77 FR 68314).

Comment: One commenter supported the proposed increase in Medicare payment for MRI-guided high intensity focused ultrasound procedures described by CPT codes 0071T and 0072T.

Response: We appreciate the commenter's support.

In summary, after consideration of the public comments we received, we are finalizing our proposal for the APC assignment of CPT code 0398T. Specifically, we are reassigning this code to New Technology APC 1575 (New Technology—Level 38 ($10,001–$15,000)), with a payment rate of $12,500.50, for CY 2019 through use of our equitable adjustment authority. In addition, we are finalizing our proposal, without modification, to assign HCPCS code C9734 to APC 5114. We also are finalizing our proposal to continue to assign CPT codes 0071T and 0072T to APC 5414, without modification. Table 17 below lists the final CY 2018 status indicator and APC assignments for MRgFUS procedures. We refer readers to Addendum B of this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

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TABLE 17.—CY 2019 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRgFUS) PROCEDURES

CPT/ HCPCS Code	Long Descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS Payment Rate	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,272.77	J1	5414	Refer to OPPS Addendum B.
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	$2,272.77	J1	5414	Refer to OPPS Addendum B.
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1576	$17,500.50	S	1575	Refer to OPPS Addendum B.

CPT/ HCPCS Code	Long Descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS Payment Rate	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	$5,606.42	J1	5115	Refer to OPPS Addendum B.

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b. Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by the Food and Drug Administration (FDA) in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large changes in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37093 through 37094), for CY 2019, the reported cost of the Argus® II procedure based on CY 2017 hospital outpatient claims data used for the CY 2019 OPPS/ASC proposed rule was approximately $152,021, which was $29,520 more than the payment rate for the procedure for CY 2018. In the proposed rule, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In

addition, the number of claims submitted has been very low and did not exceed 10 claims for CY 2017. We stated that we continue to believe that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, as discussed in section III.C.2. of the proposed rule, we proposed to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more representative of the likely cost of the service. We stated that we believe the likely cost of the Argus® II procedure is lower than the geometric mean cost calculated from the CY 2017 claims data used for the proposed rule and closer to the CY 2018 payment rate.

We analyzed claims data for the Argus® II procedure using the last 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year (CY 2015) that the Argus® II received transitional device pass-through payments and the first 2 years since device pass-through payment status for the Argus® II expired. We found the geometric mean for the procedure to be $129,891 (compared to $152,021 in CY 2017 alone), the arithmetic mean to be $134,619, and the median to be $133,679. As indicated in our proposal in section III.C.2. of the proposed rule (83 FR 37091 through 37092), we presented the result of each statistical methodology in the preamble of the proposed rule, and requested public comment on which methodology should be used to establish a payment rate. We proposed to use the arithmetic mean, which generates the highest payment rate of the three statistical methodologies, to estimate the cost of the Argus® II procedure as a means to balance the fluctuations in the costs of the procedure that have occurred from CY 2015 through CY 2017, while acknowledging the higher payment rates for the procedure in CY 2015 and CY 2017. Therefore, for CY 2019, we proposed to reassign the Argus® II procedure from APC 1904 (New Technology—Level 50 ($115,001–$130,000)) to APC 1906 (New Technology—Level 51 ($130,001–$145,000)), which resulted in a proposed payment rate for the Argus® II procedure of $137,500.50.

As we do each year, we acquired claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841).

Comment: Several commenters requested that CMS reassign CPT code 0100T to APC 1908 (New Technology—Level 52 ($145,001–$160,000)) with a payment rate of $152,500.50. The commenters were concerned that the proposed assignment of APC 1906 (New Technology—Level 51 ($130,001–$145,000)) with a payment rate of $137,500.50 will not cover all of the costs of the procedure.

Response: We have updated our payment rate for CPT code 0100T. We analyzed claims data for the Argus® II procedure using the last 3 years of available data from CY 2015 through CY 2017, which was updated with additional claims from CY 2017. These data included claims from the last year (CY 2015) that the Argus® II received transitional device pass-through payments and the first 2 years since device pass-through payment status for the Argus® II expired. We found the updated geometric mean cost for the procedure to be $145,808 (compared to $129,891 in the proposed rule), the arithmetic mean cost to be $151,367, and the median cost to be $151,266. All three of these methods of calculating the cost of the Argus® II procedure map to the cost band associated with APC 1908 (New Technology—Level 52 ($145,001–$160,000)), which has a payment rate of $152,500.50.

After reviewing the comments we received and updating our data analysis, we are reassigning the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology—Level 52 ($145,001–$160,000)) with a payment rate of $152,500.50 for CY 2019.

We discussed in the CY 2019 OPPS/ASC proposed rule that the most recent claims data available have shown another payment issue with regard to the Argus® II procedure. We have found that payment for the Argus® II procedure is sometimes bundled into the payment for another procedure. We identified two possible instances in the CY 2017 claims data in which this may have occurred. The bundling of payment for the Argus® II procedure occurs when the procedure is reported with other eye procedures assigned to a comprehensive APC (C–APC). A C–APC bundles payment for all services related to the primary service into one payment rate. We stated in the proposed rule that we were concerned that when payment for new technology services is bundled into the payment for comprehensive procedures, there is not complete claims information to estimate accurately the cost of these services to allow their assignment to clinical APCs. Therefore, we proposed to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC. This action would allow for separate payment for the Argus® II procedure even when it is performed with another comprehensive service, which would provide more cost information regarding the procedure. This proposal was also discussed in section II.A.2.c. of the proposed rule.

Comment: A number of commenters supported the proposal.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to exclude payment for all procedures assigned to New Technology APCs from being bundled into the payment for procedures assigned to a C–APC for CY 2019.

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

CMS has established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (*e.g.,* aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic

intervention(s)), effective January 1, 2019. This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure to be between $8,001 and $8,500. Therefore, we are assigning the procedure described by HCPCS code C9751 to New Technology APC 1571 (New Technology—Level 34 ($8,001–$8,500)), with a payment rate of $8,250.50 for CY 2019. Details regarding HCPCS code C9751 are shown in Table 18.

TABLE 18.—INFORMATION FOR HCPCS CODE C9751 ASSIGNED TO A NEW TECHNOLOGY APC

CY 2019 HCPCS Code	Long Descriptor	CY 2019 OPPS SI	CY 2019 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1571

D. OPPS APC-Specific Policies

1. Benign Prostatic Hyperplasia Treatments (APCs 5373 and 5374)

For the CY 2019 OPPS update, the CPT Editorial Panel established new CPT code 53854 to describe the Rezum Therapy procedure, which is also known as steam therapy or water vapor therapy, for the treatment of benign prostatic hyperplasia. Prior to January 1, 2019, the Rezum Therapy procedure was described by HCPCS code C9748, which was assigned to APC 5373 (Level 3 Urology and Related Services) when the code was established effective January 1, 2018. HCPCS code C9748 will be deleted on December 31, 2018 because it will be replaced with new CPT code 53854, effective January 1, 2019. We note that Table 19 below lists the long descriptors for both HCPCS code C9748 and CPT code 53854.

As displayed in Table 19 below, and in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to delete HCPCS code C9748 and assign the code to status indicator ''D'' to indicate that the code would be deleted for the January 2019 OPPS update. We also proposed to assign the new replacement code, CPT code 53854, to APC 5373, with a proposed payment rate of approximately $1,731. We note that the predecessor HCPCS code for CPT code 53854 (HCPCS code C9748) was also assigned to APC 5373. In addition, we note that CPT code 53854 was listed as code 538X3 (the 5-digit CMS placeholder code) in Addendum B, with the short descriptor, and in Addendum O, with the long descriptor, to the CY 2019 OPPS/ASC proposed rule. We also assigned CPT code 53854 to comment indicator ''NP'' in Addendum B to indicate that the code is new for CY 2019 with a proposed APC assignment.

Comment: Several commenters addressed the proposed APC assignment for the Rezum Therapy procedure (CPT code 53854), as well as the APC assignments for the following other benign prostatic hyperplasia treatment procedures:

- Transurethral microwave therapy (TUMT) procedure, which is described by CPT code 53850, and which we proposed to continue to assign to APC 5374 (Level 4 Urology and Related Services), with a proposed payment rate of approximately $2,756;
- Transurethral needle ablation procedure (TUNA), which is described by CPT 53852, and which we proposed to continue to assign to APC 5375 (Level 5 Urology and Related Services) with a proposed payment rate of approximately $3,776.

We note that Table 19 lists the long descriptors for the Rezum Therapy, TUMT, and TUNA procedures.

One commenter disagreed with the proposed assignment for the Rezum Therapy procedure described by CPT code 53854 to APC 5373, and indicated that APC 5373 does not contain other procedures that are similar clinically or in resource costs. The commenter stated that the Rezum Therapy procedure is comparable to the TUMT procedure, which is proposed to be assigned to APC 5374, and the TUNA procedure, which is proposed to be assigned to APC 5375. Therefore, the commenter requested that CPT code 53854, which describes the Rezum Therapy procedure, be assigned to APC 5375 instead of APC 5373. In addition, the commenter requested that the TUMT procedure described by CPT code 53850 be reassigned from APC 5374 to APC 5375. The commenter further stated that all three benign prostatic hyperplasia treatment procedures are comparable and suggested that they be assigned to APC 5375 based on clinical homogeneity and resource costs. Another commenter also believed that the Rezum Therapy procedure described by CPT code 53854 should be assigned to APC 5375.

Response: Review of our claims data used for this final rule with comment period, which is based on claims submitted between January 1, 2017 and December 31, 2017, and processed through June 30, 2018, reveals that the resource costs for these three benign prostatic hyperplasia treatment procedures are significantly different.

Our analysis shows that the geometric mean cost for CPT code 53850 (the TUMT procedure) is approximately

$3,272 (based on 107 single claims out of 107 total claims) compared to CPT code 53852 (the TUNA procedure) whose geometric mean cost is approximately $2,989 (based on 408 single claims out of 410 total claims). In addition, in September 2017, CMS received a New Technology APC application requesting a new HCPCS code for the Rezum Therapy procedure because, according to the applicant, the only available CPT code to report the procedure was CPT code 53899 (Unlisted procedure, urinary system). Based on our review of the application, assessment of the procedure, and input from our clinical advisors, we established HCPCS code C9748, effective January 1, 2018, and assigned the code to APC 5373, with a payment rate of approximately $1,696. We announced this new HCPCS C-code and APC assignment in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59320) and stated that we believed the Rezum Therapy procedure shares similar resource costs and clinical homogeneity to the other procedures assigned to APC 5373.

Further, because of the public comments received on the Rezum Therapy procedure, we conducted a preliminary claims review for HCPCS code C9748, and found that, based on 73 claims that were processed on or before July 27, 2018, the geometric mean cost for the procedure is approximately $1,711, which is significantly lower than the geometric mean cost for either CPT code 53850 (TUMT procedure) at approximately $3,272 or CPT code 53852 (TUNA procedure) at approximately $2,989.

In addition, a presenter at the August 20, 2018 HOP Panel meeting requested that the HOP Panel recommend that CMS reassign placeholder CPT code 538X3 (CPT code 53854) to APC 5374 or 5375 based on clinical similarity to the procedures described by CPT codes 53850 and 53852. Based on the information presented at the meeting, the HOP Panel made no recommendation to revise the APC assignment for the Rezum Therapy procedure. However, based on the public comments received for the reassignment for all three benign prostatic hyperplasia treatment procedures, we reviewed the procedures assigned to the family of Urology APCs for this final rule with comment period and made some modifications to more appropriately reflect the resource costs and clinical characteristics of the services within each APC grouping. Specifically, we revised the APC assignment of the procedures assigned to the family of Urology APCs to more appropriately reflect a prospective payment system that is based on payment groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity. Based on our review and modification, we revised the APC assignment for CPT code 53852 (the TUNA procedure) from APC 5375 (Level 5 Urology and Related Services) to APC 5374 (Level 4 Urology and Related Services) based on its clinical and resource homogeneity to the other procedures in the APC 5374. Specifically, our claims data show that the geometric mean cost for CPT code 53852 is approximately $2,989, which is comparable to the geometric mean cost of approximately $2,952 for APC 5374, rather than the geometric mean cost of approximately $4,055 for APC 5375. We believe that this modification to the proposed assignment of CPT code 53852 to APC 5374 is appropriate.

In addition, based on our latest claims data used for the final rule with comment period, we believe that CPT codes 53850 (the TUMT procedure) and 53852 (the TUNA procedure) are appropriately assigned to APC 5374. We also believe that, based on our assessment of the Rezum Therapy procedure and its cost, as reported in the CMS New Technology application, and based on our preliminary claims review for HCPCS code C9748 (which is the predecessor code for CPT code 53854), the Rezum Therapy procedure continues to be appropriately assigned to APC 5373 based on its clinical and resource homogeneity to the other procedures in the APC.

Comment: One commenter agreed with the proposed continued APC assignment for CPT code 53852 (the TUNA procedure) to APC 5375. The commenter also contended that, while the presenter at the August 20, 2018 HOP Panel meeting recommended an assignment of APC 5374 or APC 5375 for the procedure, the Rezum Therapy procedure is less costly to perform than the TUNA procedure, and also noted that the HOP Panel made no recommendation to CMS to change the APC assignment for either procedure.

Response: Based on our comprehensive review of the procedures assigned to the Urology APCs, and analysis of the latest claims data, we do not agree that that we should continue to assign the procedure described by CPT code 58352 (the TUNA procedure) to APC 5375 because the geometric mean cost of the procedure of approximately $2,989 is significantly less than the geometric mean cost of approximately $4,055 for APC 5375. We believe that the geometric mean cost of approximately $2,989 for the procedure described by CPT code 53852 is more comparable to the geometric mean cost of approximately $2,952 for APC 5374. Therefore, for this final rule with comment period, we are revising the proposed APC assignment for the procedure described by CPT code 58352 and assigning the procedure to APC 5374 for CY 2019.

After consideration of the public comments we received, and based on the information presented above, as well as our evaluation of the latest claims data for the TUMT, TUNA, and Rezum Therapy procedures, we are finalizing the proposed APC assignment for the procedures described by CPT code 53850 and CPT code 53854, and revising the APC assignment for the procedure described by CPT code 53852 to APC 5374 (instead of APC 5375). The final APC and status indicator assignments are listed in Table 19 below. We refer readers to Addendum B to this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 19.—PROPOSED AND FINAL CY 2019 APC AND SI ASSIGNMENTS FOR THE TUMT, TUNA, AND REZUM PROCEDURES

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Long Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC
N/A	53850	Transurethral destruction of prostate tissue; by microwave thermotherapy	J1	5374	J1	5374
N/A	53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy	J1	5375	J1	5374
538X3	53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	J1	5373	J1	5373
N/A	C9748	Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy	D	N/A	D	N/A

2. Cardiac Contractility Modulation (CCM) Therapy (APC 5231)

For CY 2019, we proposed to continue to assign the procedure described by CPT code 0408T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes) to APC 5231 (Level 1 ICD and Similar Procedures) with a proposed payment rate of approximately $22,242.

Comment: One commenter disagreed with the proposed APC assignment of the procedure described by CPT code 0408T to APC 5231 and requested that CMS assign the procedure to APC 5232 (Level 2 ICD and Similar Procedures), which had a proposed payment rate of approximately $30,862. The commenter stated that the proposed payment rate for APC 5231 does not accurately reflect the cost or clinical characteristics of the procedure and technology. The commenter added that while the procedure code has had an extremely low volume of OPPS claims, the number of claims reporting this procedure code is expected to increase in the future after the completion of a large, prospective multicenter study to evaluate CCM and its impact on the quality of life and long-term mortality in patients with moderate to severe heart failure. The commenter stated that the cost of the complete CCM system is approximately $25,000, which is comparable to the cost of an ICD system ($20,000) and CRT–D system ($30,000) whose procedure codes are assigned to APC 5232. Moreover, the commenter noted that, under the IPPS, the procedures describing the insertion of the complete system are assigned to one MS–DRG, and suggested that CMS adopt this same methodology under the OPPS. Specifically, the commenter recommended that CMS assign the procedure describing the insertion of the complete systems for the CCM, ICD, and CRT–D systems to APC 5232.

Response: The commenter suggested that we assign the procedures describing the insertion of the complete CCM, ICD, and CRT–D to one APC but did not provide the specific CPT codes associated with the ICD and CRT–D systems. Based on the information provided, we believe that the commenter is requesting that we assign to APC 5232 the following codes:

- Cardiac contractility modulation (CCM): CPT code 0408T (which we proposed in APC 5231 (Level 1 ICD and Similar Procedures));
- Implantable cardioverter-defibrillator (ICD): CPT code 33249 (which we proposed in APC 5232 (Level 2 ICD and Similar Procedures)); and
- Cardiac Resynchronization Therapy Defibrillator (CRT–D): CPT codes 33249 (which we proposed to assign to APC 5232 (Level 2 ICD and Similar Procedures) and 33225 (which we proposed to package payment because this is an add-on code), or CPT code 33270 (which we proposed to assign to APC 5232 (Level 2 ICD and Similar Procedures)).

Based on the latest hospital outpatient claims data used for this final rule with comment period, our analysis does not support the assignment of the procedures describing the insertion of the complete CCM systems (described by CPT code 0408T) to APC 5232. We examined the latest hospital outpatient claims data for CPT code 0408T for dates of service between January 1, 2017, and December 31, 2017, that were processed on or before June 30, 2018. Our analysis of the claims data show a geometric mean cost of approximately $15,131 for CPT code 0408T, based on 2 single claims (out of 2 total claims). We do not believe that it is appropriate

to assign the procedure described by CPT code 0408T to APC 5232 because its geometric mean cost is approximately $30,921, which is significantly higher than the geometric mean cost of approximately $15,131 for CPT code 0408T. Therefore, assigning the procedure described by CPT code 0408T to APC 5232 would result in an overpayment for the procedure. We believe that APC 5231 is the most appropriate APC assignment for the procedure described by CPT code 0408T based on its clinical and resource homogeneity to the other procedures assigned to this APC.

We also analyzed the latest hospital outpatient claims data for the procedure for the insertion of the complete systems for ICD and CRT–D. The insertion of a complete ICD system is described by CPT code 33249, and our analysis reveals that the geometric mean cost of approximately $33,384 for CPT code 33249 based on 29,451 single claims (out of 29,867 total claims) is significantly higher than that of CPT code 0408T whose geometric mean cost is approximately $15,131. The insertion of a complete CRT–D system is described by either CPT code 33249 or 33270. Similar to the procedure described by CPT code 33249, our findings reveal that the geometric mean cost for the procedure described by CPT code 33270 is approximately $35,361 based on 1,011 single claims (out of 1,023 total claims), which is significantly greater than that of CPT code 0408T. Based on our claims data, we do not believe that we should reassign the procedure described by CPT code 0408T (the insertion of the complete CCM systems) to APC 5232, which is the APC assignment for the insertion of the complete ICD and CRT–D systems. We believe that the geometric mean cost of approximately $15,131 for CPT code 0408T is comparable to the geometric mean cost of about $22,187 for APC 5231. We also believe that the geometric mean cost of approximately $33,384 for CPT code 33249, and the geometric mean cost of approximately $35,361 for CPT code 33270 are comparable to the geometric mean cost of approximately $30,921 for APC 5232.

Therefore, after consideration of the public comment we received, we are finalizing our proposal, without modification, to assign CPT code 0408T to APC 5231, and to continue to assign CPT code 33249 and 33270 to APC 5232 for CY 2019. The final CY 2019 payment rate for the code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As we do every year, we will reevaluate the APC assignment for CPT codes 0408T, 33249, and 33270 for the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS.

3. Cardiac Resynchronization Therapy (APCs 5221, 5222, 5231, 5731, and 5741)

In Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign eight new CY 2019 cardiac resynchronization therapy CPT codes to various APCs, which are listed in Table 20 below. The codes were listed as 06X5T, 06X6T, 06X7T, 06X8T, 06X9T, 07X2T, 06X0T, and 07X0T (the 5-digit CMS placeholder codes) in Addendum B with short descriptors and in Addendum O with long descriptors to the CY 2019 OPPS/ASC proposed rule. We also assigned these codes to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2019 with proposed APC assignments and that public comments would be accepted on their proposed APC assignments. We note that these codes will be effective January 1, 2019.

TABLE 20.—PROPOSED CY 2019 OPPS APC AND SI FOR THE CARDIAC RESYNCHRONIZATION THERAPY CPT CODES

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Short Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC
06X5T	0515T	Insj wcs lv compl sys	J1	5222
06X6T	0516T	Insj wcs lv eltrd only	T	5221
06X7T	0517T	Insj wcs lv pg	T	5221
06X8T	0518T	Rmvl pg compnt wcs	T	5221
06X9T	0519T	Rmvl & rplcmt pg compnt wcs	T	5221
07X2T	0520T	Rmvl&rplcmt pg wcs new eltrd	T	5221
06X0T	0521T	Interrog dev eval wcs ip	Q1	5731
07X0T	0522T	Prgrmg dev eval wcs ip	Q1	5741

Comment: One commenter disagreed with CMS' proposed APC assignments for certain cardiac resynchronization Category III CPT codes that are new for CY 2019 and therefore do not have associated claims data available. Specifically, the commenter requested that five of the eight new CPT codes be reassigned to the following APCs:

- CPT code 0515T (Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation

when performed; complete system (includes electrode and generator [transmitter and battery]))—from the proposed assignment to APC 5222 (Level 2 Pacemaker and Similar Procedures) to APC 5231 (Level 1 ICD and Similar Procedures);

- CPT code 0516T (Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation when performed; electrode only)—from the proposed assignment to APC 5221 (Level 1 Pacemaker and Similar Procedures) to APC 5194 (Level 4 Endovascular Procedures);
- CPT code 0517T (Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation when performed; pulse generator component(s) only (battery and/or transmitter))—from the proposed assignment to APC 5221 to APC 5222 (Level 2 Pacemaker and Similar Procedures);
- CPT code 0520T (Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter) including placement of a new electrode)—from the proposed assignment to APC 5221 to APC 5231; and
- CPT code 0521T (Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing)—from the proposed assignment to APC 5731 (Level 1 Minor Procedures) to APC 5741 (Level 1 Electronic Analysis of Devices)

First, the commenter stated that CPT codes 0515T and 0520T describe the implantation or removal/replacement of the complete system and, consequently, these procedures should be assigned to APC 5231. Second, the commenter stated that the resources associated with the procedure described by CPT 0516T are similar to those procedures described by CPT code 33274 (Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (*e.g.,* fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (*e.g.,* interrogation or programming), when performed), which is assigned to APC 5194, and, therefore, this new code should also be assigned to the same APC. In addition, the commenter indicated that the procedure described by CPT code 0517T shares the same clinical and resource homogeneity as the procedure described by CPT code 33212 (Insertion of pacemaker pulse generator only; with existing single lead), which is assigned to APC 5222, and the procedure described by CPT code 33213 (Insertion of pacemaker pulse generator only; with existing dual leads), which is assigned to APC 5223 ((Level 3 Pacemaker and Similar Procedures). Further, the commenter stated that the resources associated with the procedure described by CPT code 0521T are similar to those for the procedures described by existing CPT codes 93261 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system), CPT codes 93288 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system), 93289 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements), 93290 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors), and 93292 (Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; wearable defibrillator system), which are all assigned to APC 5741, and, consequently, the procedure described by CPT code 0521T also should be assigned to this same APC.

Response: Based on our clinical review, we agree with the commenter that there is greater homogeneity, both clinically and in terms of resource use, by assigning CPT codes 0515T and 0520T to APC 5231. We also agree with the commenter that CPT code 0517T is more homogenous clinically and in terms of resource use with the procedures assigned to APC 5222. However, we disagree with the commenter's recommendation to assign the procedure described by CPT 0516T to APC 5194. Based on our review of the procedure, we believe that CPT code 0516T is appropriately assigned to APC 5222 because of its clinical and resource homogeneity to the other procedures assigned to this APC. We also disagree with the commenter's suggestion to assign the procedure described by CPT code 0521T to APC 5741 because the resources required in performing this procedure are not as intensive as those required for the procedure described by CPT code 0522T, which we proposed to assign to APC 5741. We believe that the procedure described by CPT code 0521T is appropriately assigned to APC 5731 because of its clinical and resource homogeneity to the other procedures assigned to this APC. Table 21 below summarizes the commenter's requested APC assignment for each of the codes along with our decision and the final APC and status indicator assignments.

In summary, after consideration of the public comment we received, we are finalizing our proposal to assign the procedures described by CPT codes 0518T, 0519T, 0521T, and 0522T to the final APCs listed in Table 21 below. We are modifying our proposed APC assignment of the procedures described by CPT codes 0515T, 0516T, 0517T, and 0520T, and these modifications are reflected in the final APCs listed in Table 21 below. The final CY 2019 payment rate for CPT codes 0515T through 0521T can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

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TABLE 21.—CARDIAC RESYNCHRONIZATION THERAPY CODES WITH COMMENTER'S RECOMMENDED APCs, FINAL CMS DECISION, AND FINAL CY 2019 APC AND SI ASSIGNMENTS

CPT/ HCPCS Code	Short Descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC	Commenter Requested APC	CMS Decision	Final CY 2019 SI	Final CY 2019 APC
0515T	Insj wcs lv compl sys	J1	5222	5231	Agree with commenter	J1	5231
0516T	Insj wcs lv eltrd only	T	5221	5194	Disagree	J1	5222
0517T	Insj wcs lv pg	T	5221	5222	Agree with commenter	J1	5222
0518T	Rmvl pg compnt wcs	T	5221	5221	Same as proposal	T	5221
0519T	Rmvl & rplcmt pg compnt wcs	T	5221	5221	Same as proposal	T	5221
0520T	Rmvl&rplcmt pg wcs new eltrd	T	5221	5231	Agree with commenter	J1	5231
0521T	Interrog dev eval wcs ip	Q1	5731	5741	Disagree	Q1	5731
0522T	Prgrmg dev eval wcs ip	Q1	5741	5741	Same as proposal	Q1	5741

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4. Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, and 9094)

Chimeric Antigen Receptor (CAR) T-cell therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention.

Two CAR T-cell therapies received FDA approval in 2017. KYMRIAH® (manufactured by Novartis Pharmaceuticals Corporation) was approved for use in the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. In May 2018, KYMRIAH® received FDA approval for a second indication, treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA® (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and who have not responded to or who have relapsed after at least two other kinds of treatment.

As indicated in the CY 2019 OPPS/ASC proposed rule (83 FR 37114), the HCPCS code to describe the use of KYMRIAH® (HCPCS code Q2040) has been active since January 1, 2018 for OPPS, and the HCPCS code to describe the use of YESCARTA® (HCPCS code Q2041) has been active since April, 1, 2018 for OPPS. The HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. Both of these CAR T-cell therapies were approved for transitional pass-through payment status, effective April 1, 2018. The HCPCS codes that describe the use of these CAR T-cell therapies were assigned status indicator ''G'' in Addenda A and B to the CY 2019 OPPS/ASC proposed rule.

As discussed in section V.A.4. (Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019) of this final rule with comment period, we are finalizing our proposal to continue pass-through payment status for HCPCS code Q2040 (which is being deleted and replaced with HCPCS code Q2042, effective January 1, 2019) and HCPCS code Q2041 for CY 2019. In section V.A.4. of this final rule with comment period, we also are finalizing our proposal to determine the pass-through payment rate following the standard ASP methodology, updating pass-through payment rates on a quarterly basis if applicable information indicates that adjustments to the payment rates are necessary.

The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. As listed in Addendum B of the CY 2019 OPPS/ASC proposed rule, we proposed to assign procedures described by these CPT codes, 0537T, 0538T, 0539T, and 0540T, to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. We note that, these codes were listed as placeholder CPT codes 05X1T, 05X2T, 05X3T, and 05X4T in both Addendum B and O to the CY 2019

OPPS/ASC proposed rule. Addendum B listed the short descriptor, with the proposed status indicator of ''B'', while Addendum O listed the complete long descriptors under placeholder CPT codes 05X1T, 05X2T, 05X3T, and 05X4T. The final CPT codes and long descriptors, with their respective proposed OPPS status indicators, are listed in Table 23 at the end of this section.

At the summer 2018 meeting of the HOP Panel, the HOP Panel recommended that CMS reassign the status indicator for procedures described by these specific CPT codes from ''B'' to ''S''. The Panel further recommended that CMS assign the procedures described by CPT code 0537T and CPT code 0540T to APC 5242 (Level 2 Blood Product Exchange and Related Services), and the procedures described by CPT code 0538T and CPT code 0539T to APC 5241 (Level 1 Blood Product Exchange and Related Services).

Comment: Some commenters disagreed with the proposed status indicator assignment of ''B'' for the procedures described by CPT codes 0537T, 0538T, 0539T, and 0540T, and requested that CMS recognize these procedures and the services described by the CPT codes under the OPPS and pay separately for them. Some of these commenters urged CMS to accept and finalize the HOP Panel's recommendations for assignment of these CPT codes. Commenters stated that providers may currently use the unlisted code (38999) to bill for the services described by the new CPT codes because the currently available CPT codes fail to accurately describe the procedure being rendered. The commenters indicated that these services are similar to stem cell transplant services, and suggested that the similarities between various codes, including similarities between the procedures described by CPT code 05X1T (0537T) and CPT code 38206 (Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous), which is assigned to APC 5242 (Level 2 Blood Product Exchange and Related Services); CPT code 05X2T (0538T) and CPT code 38207 (Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage), which is assigned to APC 5241 (Level 1 Blood Product Exchange and Related Services); CPT code 05X3T (0539T) and CPT code 38208 (Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage; thawing of previously frozen harvest, without washing, per donor), which is assigned to APC 5241 (Level 1 Blood Product Exchange and Related Services), and finally CPT code 05X4T (0540T) and CPT code 38241(Hematopoietic progenitor cell (hpc); autologous transplantation), which is assigned to APC 5242 (Level 2 Blood Product Exchange and Related Services), be validly recognized and considered when determining applicable policy and assignments.

A few commenters believed that there are possible similarities between the CAR T-cell procedure CPT code 0540T and chemotherapy codes, in general. However, other commenters asserted that CAR T-cell services were distinct from the services associated with chemotherapy and stem cell transplant codes, but noted that the codes suggested were the best available approximations for payment at present and could provide useful benchmarks of resource utilization. Some commenters also supported the creation of a new Autologous HCT C–APC to adequately compensate providers for providing CAR T-cell related services. Some commenters requested that the existing Q-codes for CAR T-cell therapies be revised to reference only the CAR T-cell products, and that leukapheresis and other services related to the preparation, collection and treatment be separately coded and paid.

A few commenters referenced the National Coverage Decision (NCD) for apheresis (effective 1992), which provides coverage only under limited conditions for therapeutic apheresis, and asked CMS to clarify whether it applies to harvesting blood-derived T-lymphocytes for development of genetically modified autologous CAR T-cells. Some commenters referenced the ongoing National Coverage Analysis (NCA) for CAR T-cells, and asked CMS to provide guidance in the interim on how to bill for CAR T-cells and its therapies' administration.

The commenters also suggested additional modifications to HCPCS codes Q2040 and Q2041, such as adopting HCPCS J-codes instead of HCPCS Q-codes. Some commenters requested guidance on how to bill for specific services, incomplete services, or partial services related to CAR T-cell therapy, including but not limited to, billing for pre-infusion steps, billing for services provided a number of days before the infusion, billing if the CAR T-cell product is not infused, and billing if services are provided at different facilities, such as both inpatient and outpatient facilities.

Finally, another commenter supported the proposal not to pay separately for procedures described by CPT codes 0537T, 0538T and 0539T because the commenters maintained that payment for these CPT codes and the performance of the services describe various steps of the manufacturing process and, therefore, are appropriately included and conveyed in the descriptors of and the existence of Q-codes for CAR T-cell therapies. The commenter supported the appropriateness of including these steps in the payment for the drug as a means to ensure the manufacturer can preserve the integrity of the process and to maximize the quality of therapy. Finally, one commenter believed that separate payments for leukapheresis would increase beneficiary cost-sharing.

Response: We do not believe that separate payment under the OPPS is necessary for procedures described by CPT codes 0537T, 0538T, and 0539T. The existing CAR T-cell therapies on the market were approved as biologics and, therefore, provisions of the Medicare statute providing for payment for biologicals apply. The procedures described by CPT codes 0537T, 0538T, and 0539T describe various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological. We note that the HCPCS coding for the currently approved CAR T-cell therapy drugs, HCPCS codes Q2040 and Q2041, includes leukapheresis and dose preparation procedures because these services are included in the manufacturing of these biologicals. We also note that, for OPPS billing purposes, the Q-codes are treated in the same manner as J-codes, and a procedure assignment conversion to a J-code for payment classification purposes would not affect payment by Medicare. Q-codes can be updated quarterly, which allows for greater frequency of modifications and, therefore, we believe are appropriate for these new therapies. HOPDs can bill Medicare for reasonable and necessary services that are otherwise payable under the OPPS, and we believe that the comments in reference to payment for services provided in settings not payable under OPPS are outside the scope of the proposed rule.

With respect to NCD 110.14 for apheresis (Therapeutic Pheresis) (*https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=;82&ncdver=1&bc=AAAAgAAAAAAA&*), we note that it refers only to therapeutic treatments where blood is taken from the patient, processed, and returned to the patient as

part of a continuous procedure and is distinguished from situations where a patient is transfused at a later date. With respect to comments referencing the ongoing NCA for CAR T-cells, we remind readers that coverage analysis and determination do not determine what code or payment is assigned a particular item or service, but information on this NCA and process may be found at: *https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=291*. Accordingly, we are not revising the existing Q-codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the HOP Panel's recommendations for procedures described by CPT codes 0537T, 0538T and 0539T.

In regard to comments concerning CPT code 0540T, we were persuaded by commenters that the administration of CAR T-cell services would be more specifically described by CPT code 0540T. Because CPT code 0540T is a new code for CY 2019, we do not have any claims data on which to base our proposed payment rate. In the absence of claims data, we reviewed the clinical characteristics of the procedures to determine whether they are similar to existing procedures. After reviewing information from public commenters and input from our medical advisors, we believe that new CPT code 0540T is clinically similar to the services assigned to APC 5694 (Level IV Drug Administration), with a proposed payment rate of approximately $291, such as the procedure described by CPT code 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug). We acknowledge commenters' supporting data and indications that CAR T-cell service is complex, distinct from chemotherapy, and has the potential for highly adverse reactions. However, we note that CPT's prefatory language for the ''Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration'' section in which the procedure described by CPT code 96413, and some other services assigned to APC 5694 are listed, describes these procedures as administration of highly complex drugs or biologic agents with greater incidence of severe adverse patient reaction. We also note that the unique toxicities associated with CAR T-cell therapies tend not to occur at time of infusion, and services to monitor or treat adverse reactions on a subsequent day would not be included in the procedure described by CPT code 0540T. Therefore, we are accepting the HOP Panel's recommendation and the commenters' request to reassign the status indicator assignment of the procedure described by CPT code 0540T from ''B'' to ''S.'' However, we are not accepting the HOP Panel's recommendation and the commenters' request to assign the procedure described by CPT code 0540T to APC 5242 (Level 2 Blood Product Exchange and Related Services), but instead are assigning the procedure described by CPT code 0540T to APC 5694 (Level IV Drug Administration) for CY 2019. We remind hospitals that every year, we review the APC assignments for all services and items paid under the OPPS, and we will reevaluate the APC assignment for the procedures described by CPT code 0540T once sufficient claims data for this code become available.

Comment: Some commenters suggested that separately paying for the services described by new CPT codes for CAR T-cell therapy under the OPPS would allow Medicare and others to track utilization and cost data of these specific services. Some commenters also noted that the National Uniform Billing Committee (NUBC) established two new revenue codes and a value code related to CAR T-cell therapy, and expressed support for CMS' creation of a new CAR T-cell-related cost center (or centers) to assist with tracking CAR T-cell-related costs.

Response: The existing HCPCS codes for CAR T-cell therapies include both leukapheresis and dose-preparation procedures, and for the reasons stated previously, there is no separate payment by Medicare for these steps in the manufacturing process. However, it will be possible for Medicare to track utilization and cost data from hospitals reporting these services, even for codes reported for services in which no separate payment is made. The CAR T-cell related revenue codes and value code established by the NUBC will be reportable on HOPD claims, and will be available for tracking utilization and cost data, effective for claims received on or after April 1, 2019. At this time, we do not believe that the additional creation by CMS of a new cost center is necessary as the currently established methods for tracking CAR T-cell related costs are sufficient. However, we will monitor for this issue to determine if a distinct cost center should be established in the future.

Comment: Some commenters noted that HCPCS code Q2040 describes doses of ''up to 250 million'' cells, and requested guidance on how to bill for an adult indication that may require doses of ''up to 600 million cells.''

Response: HCPCS code Q2040 (which is being replaced by HCPCS code Q2042, effective January 1, 2019) is billed only once per infusion. For CY 2019, we revised the descriptor for HCPCS code Q2042 to describe doses ''up to 600 million cells . . . per therapeutic dose.'' For CY 2019, we also revised the descriptor for HCPCS code Q2041, in order to maintain consistency in the HCPCS coding for CAR T-cells.

In summary, after consideration of the public comments we received, we are adopting as final, without modification, the proposal to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2019. We are revising our proposal and finalizing the policy to assign status indicator ''S'' to CPT code 0540T and to assign CPT code 0540T to APC 5694 for CY 2019. Additionally, for CY 2019, we are assigning status indicator ''D'' to CPT code Q2040, status indicator ''G'' to HCPCS code Q2041, and status indicator ''G'' to HCPCS code Q2042, as summarized in Table 22 below. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2019.

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TABLE 22.–FINAL CY 2019 APC AND SI FOR HCPCS CODES Q2040, Q2041, AND Q2042

HCPCS Code	Long Descriptors	CY 2018 OPPS SI	CY 2018 OPPS APC	October 2018 OPPS Payment Rate	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC	Final CY 2019 OPPS Payment Rate
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion*	G	9081	$500,901.94	D	N/A	N/A
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose**	G	9035	$395,380.00	G	9035	Refer to OPPS Addendum B
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose				G	9194	Refer to OPPS Addendum B

* HCPCS code Q2040: As discussed above in this section, CMS deleted HCPCS Code Q2040, replaced it with HCPCS Code Q2042, and revised the long descriptor to "Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose" effective January 1, 2019."

** HCPCS code Q2041: As discussed above in this section, CMS revised the long descriptor to "Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose" effective January 1, 2019.

TABLE 23.—PROPOSED AND FINAL CY 2019 SI FOR CPT CODES 0537T, 0538T, 0539T, AND 0540T

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Long Descriptors	Proposed CY 2019 OPPS SI	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC
05X1T	0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	B	B	N/A
05X2T	0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	B	B	N/A
05X3T	0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	B	B	N/A
05X4T	0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	B	S	5694

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5. Drug-Eluting Implant (APC 5733)

For CY 2019, we proposed to continue to assign CPT code 0356T (Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each) to APC 5733 (Level 3 Minor Procedures) with a proposed payment rate of approximately $57. We also proposed to continue to assign the CPT code to status indicator ''Q1'' to indicate one of the following with regards to payment:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment.

Comment: Several commenters disagreed with the proposed continuation of the status indicator assignment of ''Q1'' for CPT code 0356T and recommended an assignment to a significant procedure status indicator instead of a conditionally packaged status indicator. One commenter indicated that the procedure described by CPT code 0356T represents a nonsurgical, independent procedure that is not based on any other primary procedure, and believed that a status indicator reassignment would ensure proper claims processing for providers.

Response: As indicated above and in OPPS Addendum D1 of the CY 2019 OPPS/ASC proposed rule, status indicator ''Q1'' represents one of three potential payment assignments. Depending on the claim submitted, and whether the procedure described by CPT code 0356T is performed with any other surgeries or services on the same day, the procedure described by CPT code 0356T may be paid separately through an APC (in this case APC 5733) or paid as part of a payment when included in the more significant procedure that is reported on the claim. Based on the nature of this procedure, which may be performed by itself or with other procedures on the same day, we believe that the continued assignment of status indicator ''Q1'' is appropriate for the procedure described by CPT code 0356T.

After consideration of the public comments we received, we are finalizing our proposal, without

modification, to assign CPT code 0356T to status indicator ''Q1'' for CY 2019. The final CY 2019 payment rate for the CPT code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

6. Endovascular Procedures (APCs 5191 Through 5194)

At the annual meeting for the HOP Panel held on August 21, 2017, the HOP Panel recommended that, for CY 2018, CMS examine the number of APCs for endovascular procedures. The HOP Panel also recommended that the appropriate Panel subcommittee review the APCs for endovascular procedures to determine whether more granularity (that is, more APCs) is warranted.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59293 through 59294), we stated that we believed that the current C–APC levels for the Endovascular Procedures C–APC family provide an appropriate distinction between the resource costs at each level and clinical homogeneity. We also stated that we would continue to review the C–APC structure for endovascular procedures to determine if any additional granularity is necessary for this C–APC family.

Using the most recent data available for the CY 2019 OPPS/ASC proposed rule, we analyzed the four existing levels of the Endovascular Procedures C–APCs. We did not observe any violations of the 2 times rule within the current Endovascular Procedures C–APC structure. Some stakeholders have suggested that for certain procedures, such as angioplasty procedures involving the use of a drug-coated balloon in addition to a nondrug-coated balloon, resource costs are significantly higher than the geometric mean cost (and associated C–APC payment) for all of the angioplasty procedures combined. We stated in the proposed rule that we recognize that the costs of a given procedure, involving additional devices, will be higher than the costs of the procedure when it does not involve such additional devices. However, the OPPS is a prospective payment system based on a system of averages in which the costs of some cases within an APC will be more costly than the APC payment rate, while the costs of other cases will be less costly. While we believe that there is sufficient granularity within the existing Endovascular Procedures C–APC structure and at least one stakeholder agrees, we stated that we have also received input from other stakeholders who have suggested alternative structures for this C–APC family that include a five-level structure and a six-level structure. An illustration of these proposed C–APC structure levels was displayed in Table 15 and Table 16, respectively, of the proposed rule. Because interested stakeholders have suggested a variety of options for the endovascular procedures C–APC structure, including keeping the existing C–APC structure, in the CY 2019 OPPS/ASC proposed rule, we proposed to maintain the existing four-level structure for this C–APC family listed in Table 14 of the proposed rule. However, we invited public comments on our proposal, as well as the stakeholder-requested five-level and six-level structures displayed in the Tables 15 and 16 of the proposed rule. We noted that the approximate geometric mean costs associated with the suggested five-level and six-level C–APC structures shown in Tables 15 and 16 of the proposed rule were only estimates and, if either of the suggested structure levels were adopted, they would be subject to change, depending on the final rule with comment period data and the particular services that are assigned to each C–APC.

Comment: Several commenters supported CMS' proposal to continue with a four-level APC structure, along with the proposed CPT code assignments to each of the endovascular APCs as described in the CY 2019 OPPS/ASC proposed rule. These commenters stated that adding additional APCs to the endovascular series could result in some APCs containing very few procedures, and further believed that this policy change would also be contrary to the concept of broader APC groupings under the OPPS. Another commenter requested that CMS provide greater detail about future proposals in order for stakeholders to be able to provide fully informed comments and recommendations.

Other commenters also agreed with CMS' assessment that the four-level APC structure and the assignment of the procedures to these APCs does not result in any 2 times rule violations, and believed that the current granularity within the existing Endovascular Procedures C–APCs' structure sufficiently represents resource cost and clinical homogeneity.

Response: We appreciate the commenters' input and support. At this time, we believe that the current APC structure levels for the Endovascular Procedures C–APC family provide an appropriate distinction between resource costs at each level and clinical homogeneity.

Comment: Several commenters believed that the current structure of the Endovascular Procedures APCs violates the 2 times rule when certain code combinations, such as the procedures described by CPT 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) and HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser), are reported in combination. As a result, the commenters requested that CMS make a complexity adjustment for CY 2019 by assigning cases for the procedures described by CPT code 37224 and HCPCS code C2623 when reported in combination with one another to APC 5193.

Some of these commenters believed that the current structure of the Endovascular Procedures APCs is insufficiently granular, and noted that the current APC structure has significant differentials in payments of over $5,000 between the current procedures assigned to Level 2 (APC 5192) and between the procedures assigned to Level 3 and Level 4 (APC 5194). These commenters further contended that the large numbers of procedures assigned to each level of APC, coupled with the high total volume of procedures assigned to each level within each APC, prevent technology costs from being adequately and accurately reflected in the OPPS payment rates. As a result, these commenters requested that CMS create a six-level structure Endovascular Procedure APC reflecting the following cost bands:

APC	Description	Approximate Cost
5191	Level 1 Endovascular APC	$2,000-$4,000
5192	Level 2 Endovascular APC	$4,000 to $6,750
519X/New 5193	Level 3 Endovascular APC	$6,750 to $9,000
5193/New 5194	Level 4 Endovascular APC	$9,000-$11,000
519Y/New 5195	Level 5 Endovascular APC	$11,000 to $14,000
Current 5194/New 5196	Level 6 Endovascular APC	$14,000+

Some of these commenters also specifically suggested that the procedures described by CPT code 37224 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty) and HCPCS code C2623 (Catheter, transluminal angioplasty, drug-coated, non-laser); and CPT code 37726 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) and HCPCS code C1874 (Stent, coated/covered, with delivery system) be assigned to the newly leveled structure within APC 5193 and APC 5195, respectively, in order to take into consideration the performance of and utilization of procedures involving drug-coated balloons and drug eluting stents that are required for these procedures.

Several of these same commenters requested that CMS create new HCPCS code modifiers to take into account the performance of the procedures described by CPT code 37724 when reported in combination with HCPCS code C2623, and CPT code 37226 when reported in combination with HCPCS code C1874. The commenters provided that CMS could model the costs for these cases using CY 2017 and CY 2018 claims data when these codes are reported in combination with one another. The commenters further believed that the creation of new HCPCS code modifiers are necessary in order to differentiate drug-coated device procedures from non-drug-coated device procedures, and will provide the granularity in HCPCS and APC coding that will allow CMS to collect data for the CPT/HCPCS codes to appropriately calculate payment rates within the APCs. Another commenter further stated that these procedures should be assigned to the newly created APC 5193 and APC 5195, respectively.

Response: We appreciate the commenters' suggestion. As noted in the proposed rule, we understand that some stakeholders have suggested that when certain procedures, such as those described by CPT code 37224 and HCPCS code C2623 are reported in combination, a 2 times rule violation occurs. However, we recognize that the costs of a given procedure, involving additional devices, will be higher than the costs of the procedure when it does not involve such additional devices, and we do not believe that these types of 2 times rule violations are avoidable, given the nature of a prospective payment system (83 FR 37095).

Using the most recent data available for this final rule with comment period, we analyzed the various alternative suggestions for the recommended HCPCS code placements, including maintaining the CY 2018 APC groupings, creating a six-level APC, and reconfiguring significant HCPCS code placements within the current structure. We note that, when we modeled the creation of a six-level structure APC and modeled a reconfiguration of significant HCPCS code placements, we noticed significant downward payment fluctuations for several services, some as high as a $2,500 decrease relative to the payment rate in CY 2018. Furthermore, based on these findings, we are still not convinced that we should pay for a complexity adjustment for the procedure described by CPT code 37224 when reported in combination with HCPCS code C2623 or for the procedure described by CPT code 37226 when reported in combination with HCPCS code C1874. As noted above and as provided in the proposed rule, the OPPS is a prospective payment system based on a system of averages in which the costs of some cases within an APC will be more costly than the APC payment rate, while the costs of other cases will be less costly and in these particular procedures we believe that if a complexity adjustment would be applied it would adversely affect the APC payment (83 FR 37095). Additionally, at this time, we do not support the creation of any new HCPCS codes for inclusion in the Endovascular Procedures APCs. Specifically, we do not believe that we have the needed evidence and data to support combining payment for either the procedure described by CPT code 37724 when reported in combination with HCPCS code C2623 or the procedure described by CPT code 37226 when reported in combination with HCPCS code C1874 because we believe that payment for these services are currently adequate.

However, we do share similar concerns with the commenters regarding the significant differential payments between the procedures assigned within the current four-level structure of the Endovascular Procedures APCs and intend to revisit this particular issue in future rulemaking. Therefore, after consideration of the public comments and suggestions we received, we are maintaining the CY 2018 APC structure of four levels for the Endovascular Procedures APCs. We understand the importance of payment stability for providers and believe that continuation of the four levels within the Endovascular Procedures APCs will minimize fluctuation in payment rates from CY 2018 to CY 2019. As displayed in the ''Two Times Listing'' file to this final rule with comment period, which is available via the internet on the CMS website, the APC geometric mean costs for APCs 5521 through 5524 are consistent with the CY 2018 APC geometric mean costs for the same APCs, indicating the relative weights that are used to calculate payment are stable.

We will continue to review this APC structure to determine if additional granularity is necessary for this C–APC family, including if additional HCPCS codes should be created in future rulemaking. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. Additionally, we refer readers to Addendum A to this final rule with comment period for the complete list of APCs and their payment rates under the OPPS. Both Addendum A and Addendum B are available via the internet on the CMS website.

TABLE 24.—CY 2019 C-APC STRUCTURE FOR ENDOVASCULAR PROCEDURES

C-APC	Geometric Mean Cost
5191 – Level 1 Endovascular Procedures	$2,834
5192 – Level 2 Endovascular Procedures	$4,719
5193 – Level 3 Endovascular Procedures	$9,752
5194 – Level 4 Endovascular Procedures	$15,487

7. Fine Needle Aspiration Biopsy (APC 5071)

As displayed in Table 25 below and in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign CPT codes 10009 and 10011 to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage), with a proposed payment rate of approximately $582. The codes were listed as 10X16 and 10X18 (the 5-digit CMS placeholder codes), respectively, in Addendum B with the short descriptors and in Addendum O with the long descriptors to the CY 2019 OPPS/ASC proposed rule. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2019, with proposed APC assignments, and that public comments would be accepted on their proposed APC assignments. We note that these codes will be effective January 1, 2019.

Comment: One commenter disagreed with the proposed assignment of the procedure described by CPT code 10009 to APC 5071 and suggested that APC 5072 (Level 2 Excision/Biopsy/Incision and Drainage), with a proposed payment rate of approximately $1,370, is more appropriate because the resource cost of the CT guidance used in the procedure is higher than the resource cost of ultrasound or fluoroscopy. The commenter disagreed with the proposed assignment of the procedure described by CPT code 10011 to APC 5071 and recommended that APC C–5373 (Level 3 Urology and Related Services), with a proposed payment rate of approximately $1,731, is more appropriate because the cost of the MRI guidance used in the procedure is clinically similar to the other services in this APC.

Response: Because CPT codes 10009 and 10011 are new codes for CY 2019, we do not have claims data on which to base the payment rates. However, in the absence of claims data, we reviewed the clinical characteristics of the procedures described by CPT codes 10009 and 10011 to determine whether they are similar to existing procedures. After reviewing information from the public commenter and input from our medical advisors, we believe that the procedures described by new CPT codes 10009 and 10011 are clinically similar to those procedures assigned to APC 5071. We are unclear of the rationale for the commenter's suggestion of recommending a Urology APC assignment (C–APC 5373) for the procedure described by CPT code 10011 when this procedure describes a fine needle aspiration biopsy, which is not a urology-specific procedure. Therefore, we are not accepting the commenter's recommendation. In addition, we remind hospitals that, every year, we review the APC assignments for all services and items paid under the OPPS. We will reevaluate the APC assignment for the procedures described by CPT codes 10009 and 10011 once we have claims data for the codes.

After consideration of the public comment received, we are finalizing our proposal, without modification, to assign the procedures described by CPT codes 10009 and 10011 to APC 5071 for CY 2019. The final APC and status indicator assignments are listed in Table 25 below. We refer readers to Addendum B of this final rule with comment period for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 25.—PROPOSED AND FINAL CY 2019 APC AND SI ASSIGNMENTS FOR CPT CODES 10009 AND 10011

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Long Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC
10X16	10009	Fine needle aspiration biopsy, including CT guidance; first lesion	T	5071	T	5071
10X18	10011	Fine needle aspiration biopsy, including MR guidance; first lesion	T	5071	T	5071

8. Fluorescence In Situ Hybridization (FISH) Assays (APCs 5672 and 5673)

As displayed in Table 26 below and in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign the procedures described by CPT codes 88364 through 88377 to status indicator ''N'' to indicate a packaged payment status, or status indicators ''Q1'' and ''Q2'' to indicate a conditionally packaged payment status, with APC assignments to either APC 5672 (Level 2 Pathology), with a proposed payment rate of approximately $145, or APC 5673 (Level 3 Pathology), with a proposed payment rate of approximately $273.

Comment: One commenter urged CMS to exclude certain FISH assays from the OPPS packaging policy. Specifically, the commenter stated that the technical component of services that are associated with the services described by CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377 have unique clinical utilization that is distinct from conventional laboratory tests, and suggested that the services described by these codes be excluded from the OPPS payment packaging policy. The commenter further stated that these tests are utilized in both the hospital outpatient and hospital inpatient setting similar to molecular pathology tests and advanced diagnostic laboratory tests (ADLTs).

Response: As stated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79593), payment for most laboratory tests is packaged under OPPS. Under our current policy, payment for certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) is packaged in the OPPS as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting (81 FR 79593 and 42 CFR 419.2(b)(17)). However, we have established exceptions to the OPPS laboratory test packaging policy for molecular pathology tests, certain ADLTs, and preventive laboratory tests. Specifically, we exclude from packaging the following laboratory tests:

- Molecular pathology tests, because these relatively new tests may have a different pattern of clinical use than more conventional laboratory tests, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged (80 FR 70348 through 70350);
- ADLTs, as designated under the CLFS, that meet the criteria of section 1834A(d)(5)(A) of the Act (81 FR 79593 through 79594), and
- Preventive laboratory tests that are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. 100–04) (80 FR 70349).

We note that laboratory tests also are paid separately when they are the only services provided to a beneficiary on a claim (81 FR 79593). When payment for laboratory tests is not packaged under the OPPS, and the tests are listed on the CLFS, the payment is made at the CLFS payment rates, outside the OPPS, under Medicare Part B.

With regard to the services described by CPT codes 88364, 88369, and 88373, we proposed to continue to assign these add-on services to status indicator ''N'' because, under the OPPS, payment for services described by add-on codes are packaged in accordance with the regulations at § 419.2(b)(18).

In addition, with regard to the services described by CPT codes 88365, 88366, 88374, and 88377, we proposed to continue to assign these codes to status indicator ''Q1'' to indicate that these services are separately payable when not billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''. Further, with regard to the services described by CPT codes 88367 and 88368, we proposed to continue to assign these codes to status indicator ''Q2'' to indicate that payment for these services will be packaged in the APC payment if billed on the same date of service as a HCPCS code assigned to status indicator ''T'', but in all other circumstances, separate APC payment for the services would be made. Based on the nature of these services, we believe the payment for the services described by CPT codes 88365, 88366, 88367, 88368, 88374, and 88377 should continue to be conditionally packaged under the OPPS because these laboratory tests may be performed with other procedures on the same day.

In summary, because the services described by CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377 are not molecular pathology laboratory tests, ADLTs, or preventive laboratory tests as stated in the above response, we believe that we should continue to package the payment for these services under the OPPS. Therefore, after consideration of the public comment received, we are finalizing our proposal, without modification, to assign the services described by CPT codes 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, and 88377 to the final APCs and status indicator assignments listed in Table 26 below. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website. In addition, we refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2019.

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TABLE 26.—PROPOSED AND FINAL CY 2019 APC AND SI ASSIGNMENTS FOR CPT CODES 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, AND 88377

HCPCS Code	Short Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Proposed CY 2019 OPPS Payment Rate	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC	Final CY 2019 OPPS Payment Rate
88364	Insitu hybridization (fish)	N			N	N/A	
88365	Insitu hybridization (fish)	Q1	5672	$144.65	Q1	5672	Refer to OPPS Addendum B
88366	Insitu hybridization (fish)	Q1	5673	$271.73	Q1	5673	Refer to OPPS Addendum B
88367	Insitu hybridization auto	Q2	5673	$271.73	Q2	5673	Refer to OPPS Addendum B
88368	Insitu hybridization manual	Q2	5673	$271.73	Q2	5673	Refer to OPPS Addendum B
88369	M/phmtrc alysishquant/semiq	N			N	N/A	
88373	M/phmtrc alys ishquant/semiq	N			N	N/A	
88374	M/phmtrc alys ishquant/semiq	Q1	5672	$144.65	Q1	5672	Refer to OPPS Addendum B
88377	M/phmtrc alys ishquant/semiq	Q1	5672	$144.65	Q1	5672	Refer to OPPS Addendum B

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9. Immediate Breast Implant Following Mastopexy/Mastectomy (C–APC 5092)

For CY 2019, we proposed to continue to assign the procedures described by CPT code 19340 (Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction) to C–APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures), with a proposed payment rate of approximately $4,960.

Comment: Some commenters disagreed with the proposed continued APC assignment for the procedure described by CPT code 19340 to C–APC 5092 and suggested instead a reassignment to C–APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures), with a proposed payment rate of approximately $7,432. One commenter believed that the procedure described by CPT code 19340 shares similar clinical and resource characteristics as the procedures described by CPT codes 19325 (Mammaplasty, augmentation; with prosthetic implant) and 19342 (Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction), which are assigned to C–APC 5093. Another commenter requested a review and reconfiguration of C–APCs 5092 and 5093, and believed

that the cost of performing the procedure described by CPT code 19340 is similar to the surgical procedures assigned to C–APC 5093.

Response: Analysis of the hospital outpatient claims data used for this final rule with comment period, which is based on claims submitted between January 1, 2017 and December 31, 2017, and processed through June 30, 2018, do not support a reassignment of the procedure described by CPT code 19340 to C–APC 5093. Specifically, our claims data show a geometric mean cost of approximately $5,341 for the procedure described by CPT code 19340 based on 1,187 single claims (out of 1,203 total claims), which is comparable to the geometric mean cost of approximately $4,958 for C–APC 5092. In contrast, our claims data show a higher geometric mean cost for the procedures described by CPT codes 19325 (approximately $6,326 based on 209 single claims out of 210 total claims) and 19342 (approximately $6,232 based on 1,190 single claims out of 1,202 total claims) that is comparable to the geometric mean cost of approximately $7,513 for C–APC 5093. Based on our analysis, we believe that the procedure described by CPT code 19340 is appropriately assigned to C–APC 5092 based on resource and clinical homogeneity to the other procedures in the APC. We note that all of the procedures described by CPT codes assigned to this Breast/Lymphatic Surgery and Related Procedures C–APC are clinically similar and that the resource similarity is based on the geometric mean costs derived from claims submitted by hospitals performing these procedures.

After consideration of the public comments we received and based on our analysis of the latest hospital outpatient claims data for the procedures described by CPT codes 19340, 19325, and 19342, we are finalizing our proposal, without modification, to continue to assign CPT code 19340 to C–APC 5092. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

10. Intracardiac Ischemia Monitoring (APCs 5221, 5222, 5223, and 5741)

In Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign eight new intracardiac ischemia monitoring CPT codes to various APCs, which are listed in Table 27 below. The codes were listed as 00X0T through 00X7T (the 5-digit CMS placeholder codes) in Addendum B with short descriptors and in Addendum O with long descriptors to the CY 2019 OPPS/ASC proposed rule. We also assigned these codes to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2019, with proposed APC assignments, and that public comments would be accepted on their proposed APC assignments. We note these codes will be effective January 1, 2019. Although the codes are new for CY 2019, the services associated with intracardiac ischemia monitoring were previously described by CPT codes 0302T through 0307T, which were deleted on December 31, 2017.

TABLE 27.—PROPOSED CY 2019 OPPS APC AND SI ASSIGNMENTS FOR THE INTRACARDIAC ISCHEMIA MONITORING CPT CODES

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Short Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC
00X0T	0525T	Insj/rplcmt compl iims	J1	5223
00X1T	0526T	Insj/rplcmt iims eltrd only	J1	5222
00X2T	0527T	Insj/rplcmt iims implt mntr	J1	5222
00X3T	0528T	Prgrmg dev eval iims ip	Q1	5741
00X4T	0529T	Interrog dev eval iims ip	Q1	5741
00X5T	0530T	Removal complete iims	Q2	5221
00X6T	0531T	Removal iims electrode only	Q2	5221
00X7T	0532T	Removal iims implt mntr only	Q2	5221

Comment: One commenter disagreed with CMS' proposed APC assignment for the new intracardiac ischemia monitoring Category III CPT code 0525T (Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)) and requested assignment to APC 5224 (Level 4 Pacemaker and Similar Procedures) instead of APC 5223. The commenter suggested that the procedure described by CPT code 0525T be assigned to APC 5224, which is the same APC that was assigned to its predecessor CPT code 0302T (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation when performed and intra-operative interrogation and programming when performed; complete system (includes device and electrode)) when the code was active during CY 2017. The commenter also stated that the procedure described by CPT code 0525T is more complex and requires significantly more resources than the other procedures assigned to APC 5223. The commenter further indicated that the cost of the Guardian System alone, which is related to the CPT codes of concern, is between $8,000 to $8,700, while the overall cost for the insertion of the complete system is between $15,700 and $16,400.

Response: For CY 2018, CMS received a New Technology APC application requesting a new HCPCS code for the insertion of an intracardiac ischemia monitoring system because no current CPT code existed to describe the procedure, and because its predecessor CPT code 0302T was deleted on December 31, 2017. Based on our review of the application, evaluation of the procedure, and input from our clinical advisors, we agreed that no existing code appropriately describes the insertion of an intracardiac ischemia monitoring system and, therefore, established HCPCS code C9750 (Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation and peri-operative interrogation and programming; complete system (includes device and electrode)), effective October 1, 2018. For the October 2018 OPPS update, we assigned HCPCS code C9750 to APC 5223 (Level 3 Pacemaker and Similar Procedures) with a payment rate of approximately $9,748. We announced this new HCPCS code and APC assignment in the October 2018 OPPS quarterly update CR (Transmittal 4123, Change Request 10923, dated August 24, 2018). Because the procedure described by CPT code 0525T is the same procedure described by HCPCS code C9750, we proposed to assign CPT code 0525T to APC 5223.

In addition, we reviewed our claims data for the predecessor CPT code 0302T that were submitted during CY 2012 through CY 2017. We note that predecessor CPT code 0302T became effective July 1, 2012 and was deleted on December 31, 2017. Our analysis of the claims data for CPT code 0302T revealed no single claim submitted for CY 2017, CY 2016, CY 2014, CY 2013, or CY 2012. We did find one claim that was submitted during CY 2015 with a geometric mean cost of approximately $4,619. However, based on cost information submitted to CMS in the New Technology APC application, we believe that APC 5223, whose geometric mean cost is approximately $9,964, is the appropriate APC assignment for the procedure described by CPT code 0525T. We believe that the procedure described by CPT code 0525T shares similar resource and clinical homogeneity to the other procedures currently assigned to APC 5223. Consequently, we did not assign the code to a New Technology APC because the services assigned to APC 5223 are clinically similar to the service described by CPT code 0525T. Therefore, we believe that APC 5223 is the more appropriate APC assignment for the procedure described by CPT code 0525T.

Comment: One commenter also disagreed with the proposed assignment of the service described by CPT code 0528T to APC 5741, and requested that the service be assigned to APC 5743 (Level 3 Electronic Analysis of Devices) instead. The commenter stated that the service generally takes about 60 minutes to perform, which is similar to the following services assigned to APC 5743:

- CPT code 0462T (Programming device evaluation (in person) with iterative adjustment of the implantable mechano-electrical skin interface and/or external driver to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable aortic counterpulsation ventricular assist system, per day);
- CPT code 0463T (Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable aortic counterpulsation ventricular assist system, per day); and
- CPT code 0472T (Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (*e.g.,* retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional).

Response: Based on our review of the predecessor CPT codes for the intracardiac ischemia monitoring systems that were in existence from July 1, 2012 through December 31, 2017, we found that the service described by CPT code 0528T (Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report) was previously described by predecessor CPT code 0305T (Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report). Similar to predecessor CPT code 0302T, predecessor CPT code 0305T became effective July 1, 2012 and was deleted on December 31, 2017. Our analysis of the claims data for the service described by CPT code 0305T revealed no single claim submitted during CY 2012 through CY 2017. Based on input from our medical advisors and our APC assignment for predecessor CPT code 0305T to APC 5741, we believe that APC 5741 is the appropriate APC assignment for the service described by CPT code 0528T, based on similar programming device evaluation codes assigned to this APC.

In summary, after consideration of the public comment we received, we are finalizing our proposal, without modification, to assign the services described by CPT codes 0525T through 0532T to the final APCs listed in Table 28 below. We note that HCPCS code C9750 will be deleted December 31, 2018, because it will be replaced with CPT code 0525T, effective January 1, 2019. The final CY 2019 payment rate for CPT codes 0525T through 0532T can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

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TABLE 28.—FINAL CY 2019 OPPS APCs AND STATUS INDICATORS (SI) FOR THE INTRACARDIAC ISCHEMIA MONITORING CPT CODES

CY 2019 CPT Code	Long Descriptor	Final CY 2019 SI	Final CY 2019 APC
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	J1	5223
0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	J1	5222
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	J1	5222
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	Q1	5741
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	Q1	5741
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	Q2	5221
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only	Q2	5221
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only	Q2	5221

11. Intraocular Retinal Electrode Programming and Reprogramming (APCs 5742 and 5743)

As noted in Table 29 below, for CY 2019, we proposed to continue to assign the procedure described by CPT code 0472T to APC 5743 (Level 3 Electronic Analysis of Devices), with a proposed payment rate of approximately $280. We also proposed to continue to assign the procedure described by CPT code 0473T to APC 5742 (Level 2 Electronic Analysis of Devices), with a proposed payment rate of approximately $115.

Comment: One commenter supported CMS' proposal to continue to assign the programming services for Argus II, which are described by CPT codes

0472T and 0473T, to APCs 5743 and 5742.

Response: We appreciate the commenter's support. Based on input from our medical advisors, we believe that CPT codes 0472T and 0473T are appropriately assigned to APCs 5743 and 5742, respectively, based on clinical and resource homogeneity to the other services assigned to these APCs.

Therefore, after consideration of the public comment received, we are finalizing our proposal, without modification, to continue to assign the procedures described by CPT codes 0472T and 0473T to APCs 5743 and APC 5742, respectively, for CY 2019. The final APC and status indicator assignments are listed in Table 29 below. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 29.—PROPOSED AND FINAL CY 2019 APC AND SI ASSIGNMENTS FOR CPT CODES 0472T AND 0473T

CPT Code	Long Descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC	Final CY 2019 SI	Final CY 2019 APC
0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional	Q1	5743	Q1	5743
0473T	Device evaluation and interrogation of intraocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional	Q1	5742	Q1	5742

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12. Kidney Dilation of Tract (C–APC 5373)

In Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign the procedure described by CPT code 50436 (Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed) to C–APC 5373 (Level 3 Urology and Related Services), with a proposed payment rate of approximately $1,731. This code was listed as 50X39 (the 5-digit CMS placeholder code) in Addendum B, with the short descriptor, and in Addendum O, with the long descriptor, to the CY 2019 OPPS/ASC proposed rule. We also proposed to assign this code to comment indicator ''NP'' in Addendum B to indicate that the code is new for CY 2019 with a proposed APC assignment and that public comments would be accepted on the proposed APC assignment. We note that this code will be effective January 1, 2019.

Comment: One commenter disagreed with the proposed assignment of CPT code 50436 to C–APC 5373 and instead recommended assignment to C–APC 5374 (Level 3 Urology and Related Services), with a proposed payment rate of approximately $2,755, because of the higher resource costs associated with the procedure.

Response: Because CPT code 50436 is a new code for CY 2019, we do not have claims data on which to base a payment rate. However, in the absence of claims data, we reviewed the clinical characteristics of the procedure to determine whether the surgical procedure is similar to existing procedures. After review of the procedure and input from our clinical advisors, we believe that the procedure described by new CPT code 50436 is clinically similar to those procedures assigned to C–APC 5373. We will reevaluate the APC assignment for the procedure described by CPT code 50436 once claims data for this procedure become available. We note that as we do every year, we review the APC assignments for all services and items paid under the OPPS.

After consideration of the public comment we received, we are finalizing our proposal to assign the procedure described by CPT code 50436 to C–APC 5373. We refer readers to Addendum B of this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

13. Intraocular Procedures (APC 5494)

In prior years, the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) has been assigned to the APC 5495 (Level 5

Intraocular Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median under our payment policy for low-volume device-intensive procedures established in the CY 2016 OPPS because the APC contained a low volume of claims. The low-volume device-intensive procedures policy is discussed in more detail in section III.C.2. of the proposed rule and this final rule with comment period.

In reviewing the claims data available for the proposed rule for CY 2019 OPPS ratesetting, we found that there were only two claims containing procedures described by CPT code 0308T, with a geometric mean of $5,438.99 and a median of $8,237.56. Based on those two claims, APC 5495 would have had a proposed geometric mean of $5,438.99 and a proposed median of $8,237.56. However, based on its estimated costs in the most recently available claims data, we stated in the proposed rule that we believe that the procedure described by CPT code 0308T is more appropriately placed in the APC 5493, which has a geometric mean cost of $9,821.47, which is more comparable to that of the procedure described by CPT code 0308T. Therefore, for CY 2019, we proposed to reassign the procedure described by CPT code 0308T from APC 5495 to APC 5493 (Level 3 Intraocular Procedures) and to delete APC 5495. We stated that we would continue to monitor the volume of claims reporting a procedure described by CPT code 0308T available to us for future ratesetting.

Comment: One commenter requested that the procedure described by CPT code 0308T be assigned to a New Technology APC based on the proposed low-volume New Technology policy, without requesting a specific New Technology APC or cost band. The commenter believed that the reasons for developing the low volume New Technology policy are consistent with issues related to the procedure described by CPT code 0308T, including the quality and volume of claims data, and resulting cost fluctuation. The commenter noted that because those issues facing low-volume procedures would be the same, regardless of whether the procedures are assigned to a New Technology or clinical APC, it would be appropriate to assign the procedure described by CPT code 0308T to a New Technology APC. However, the commenter requested that, if that change were not to be made, CMS instead assign the procedure described by the CPT code to APC 5495, which was previously for ''Level 5 Intraocular Procedures'' and that the same smoothing methodology for low volume New Technology procedures, which includes use of multiple years of claims data, apply to the procedure described by CPT code 0308T, given its low volume.

Response: In previous years, the procedure described by CPT code 0308T was assigned to APC 5495 (Level 5 Intraocular Procedures) using a median-based weight under the low-volume device intensive policy. Based on the CY 2017 claims data available for ratesetting, in the CY 2019 OPPS/ASC proposed rule, we proposed to assign the procedure described by CPT code 0308T to APC 5493, noting that we would continue to monitor the data. In the CY 2019 OPPS final rule claims data, the estimated cost of the single claim with CPT code 0308T as the primary service is approximately $12,939.75.

While we appreciate the stakeholder's comments regarding changes in estimated costs based on the claims data available for ratesetting, we have concerns with establishing a New Technology APC methodology for a clinical APC especially in the absence of a New Technology application, which is used to evaluate new technology APC requests. We also note that the procedure described by CPT code 0308T has historically been assigned to a clinical APC beginning with the CY 2013 OPPS.

Recognizing the estimated cost based on the final rule claims data and the commenter's concerns, we believe that the procedure described by CPT code 0308T is appropriate for assignment to clinical APC 5494 (Level 4 Intraocular Procedures). CPT code 0308T has device-intensive status based on its device offset percentage and the fact that the APC to which the procedure is assigned has fewer than 100 total claims. Therefore, the low-volume device intensive policy of using the median cost for OPPS ratesetting would apply.

After consideration of the public comment we received, we are modifying our proposal to assign the procedure described by CPT code 0308T to APC 5493 and instead are assigning the procedure described by CPT code 0308T to APC 5494 (Level 4 Intraocular Procedures) for CY 2019.

14. Magnetocardiography

As displayed in Table 30 below and in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign the services described by CPT codes 0541T and 0542T to status indicator ''E1'' to indicate that these codes are not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services associated with these codes are either not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. The codes were listed as 0X01T and 0X02T (the 5-digit CMS placeholder codes), respectively, in Addendum B, with the short descriptors, and in Addendum O, with the long descriptors, to the CY 2019 OPPS/ASC proposed rule. We also assigned these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2019 and that public comments would be accepted on their proposed status indicator assignments. We note that these codes will be effective January 1, 2019.

Comment: One commenter disagreed with the proposed status indicator assignment of ''E1'' for CPT codes 0541T and 0542T, and stated that the technology was approved by the FDA. The commenter explained that these codes describe magnetocardiography (MCG), which is a ''high-fidelity biomagnetic imaging technique that utilizes highly sensitive magnetometers and a compact shield in order to measure, image and analyze the repolarization patterns of the heart.'' The commenter also indicated that MCG may be used to replace or avoid the need for additional cardiac stress and related testing, myocardial perfusion imaging, and/or PET procedures, and rapidly triage patients who present to the ED with chest pain or other symptoms of cardiac ischemia.

Because the technology has been approved by the FDA, the commenter requested that CMS assign the procedures described by both CPT codes to APC 5593 (Level 3 Nuclear Medicine) or APC 5724 (Level 4 Diagnostic Tests and Related Services). Although the commenter requested an assignment to either APC 5593 or 5724, the commenter also noted that the services described by CPT codes 0541T and 0542T are clinically comparable to the services that are assigned to the following three APCs:

- APC 5593 (Level 3 Nuclear Medicine), with a proposed payment rate of approximately $1,228, which includes—
  - CPT code 78451 (Myocardial perfusion imaging); and
  - CPT code 78452 (Myocardial perfusion imaging)
- APC 5594 (Level 4 Nuclear Medicine), with a proposed payment rate of approximately $1,386, which includes—

○ CPT code 78491 (Positron Emission Tomography (PET) myocardial functional imaging); and

○ CPT code 78492 (Positron Emission Tomography (PET) myocardial functional imaging)

• APC 5724 (Level 4 Diagnostic Tests and Related Services), with a proposed payment rate of approximately $918, which includes—

○ CPT code 95965 (Magnetoencephalography (MEG)); and

○ CPT code 95966 (Magnetoencephalography (MEG))

In addition to the requested APC assignment, the commenter requested that CMS assign the codes status indicator ''S'' (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment), instead of status indicator ''E1'', similar to the status indicator assignment for the comparable codes in APCs 5593, 5594, and 5724.

Response: Based on our understanding of the procedure, we found that the service associated with these codes are currently in clinical trial (Study Title: ''Magnetocardiography Using a Novel Analysis System (Cardioflux) in the Evaluation of Emergency Department Observation Unit Chest Pain Patients''; *ClinicalTrials.gov* Identifier: NCT03255772). Further review of the clinical trial revealed that the clinical study has not yet met CMS' standards for coverage, nor does it appear on the CMS Approved IDE List, which can be found at this CMS website: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html*. Moreover, based on our review associated with the technology, we have not found evidence of FDA approval or clearance of the Cardioflux System as it appears that an application is pending with FDA, even though predicate devices have already been approved and are on the market. Because this specific MCG technology has not been approved for Medicare coverage or cleared by the FDA, we believe that we should continue to assign the procedures described by CPT codes 0541T and 0542T to status indicator ''E1'' for CY 2019. If this technology later meets CMS' standards for coverage, we will reassess the APC assignment for the codes in a future quarterly update and/or rulemaking cycle.

Therefore, after consideration of the public comment received, we are finalizing our proposal, without modification, for the assignment of status indicator ''E1'' to the procedures described by CPT codes 0541T and 0542T. The final status indicator assignment for both codes is listed in Table 30 below. We refer readers to Addendum D1 of this final rule with comment period for the complete list of the OPPS payment status indicators and their definitions for CY 2019. Addendum D1 is available via the internet on the CMS website.

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TABLE 30.—PROPOSED AND FINAL CY 2019 SI FOR CPT CODES 0541T AND 0542T

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	CY 2019 Long Descriptor	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Final CY 2019 OPPS SI	Final CY 2019 OPPS APC
0X01T	0541T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic field time series images, quantitative analysis of magnetic dipoles, machine learning derived clinical scoring, and automated report generation, single study;	E1	N/A	E1	N/A
0X02T	0542T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic field time series images, quantitative analysis of magnetic dipoles, machine learning derived clinical scoring, and automated report generation, single study; interpretation and report	E1	N/A	E1	N/A

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15. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal Procedures APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and to provide clinical homogeneity. However, we also indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

While we did not propose any changes to the 2019 OPPS structure of the Musculoskeletal Procedures APC series in the CY 2019 OPPS/ASC proposed rule, we stated that we recognize that commenters have previously expressed concerns regarding the granularity of the current APC levels and requested establishment of additional APC levels. Therefore, we solicited public comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal Procedures APC series.

Table 18 of the proposed rule listed the Musculoskeletal Procedures APCs, the HCPCS codes assigned to the APCs, and the proposed APC geometric mean cost.

Comment: Many commenters requested that CMS maintain the current six-level APC structure. Some of these commenters stated that the current structure provides sufficient granularity in the APCs, while other commenters suggested that, because Medicare previously made changes to create additional APCs in the Musculoskeletal Procedures APC series in the CY 2016 and CY 2017 OPPS, CMS delay any additional changes. Some commenters requested that CMS create additional levels and assign specific codes to either the new levels or existing levels within the relative structure. One commenter requested CMS maintain the procedure described by CPT code 27279 (Arthrodesis sacroiliac joint) at the highest level APC based on its geometric mean cost, if any additional high cost APC level above the current Level 6 were created. Another commenter requested that CMS create additional intermediate levels between the existing APC Levels 4 and 5 and between Levels 5 and 6, and assign the procedures described by CPT code 28740 (Fusion of foot bones) and CPT code 28297 (Correction hallux valgus) to the new APC level between Levels 4 and 5. One commenter requested that, if a level were to be created between the current Levels 5 and 6, the procedure described by CPT code 27447 (Total knee arthroplasty) be assigned to that APC level. Other commenters requested that total knee arthroplasty be assigned to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) for CY 2019, which has a payment rate at $12,500 based on their analysis of the costs of the procedure for only those claims that reported certain device costs, rather than using all claims to calculate the geometric mean costs of the service.

Response: We appreciate the commenters' support for maintaining the current APC structure. While we have previously stated that we believe that the six level APC structure for the Musculoskeletal Procedures APC series remains appropriate in providing distinction between resource costs at each level and clinical homogeneity (82 FR 59300), in the CY 2019 proposed rule, we solicited comment on whether additional levels might be appropriate based on stakeholder concerns (83 FR 37096). Based on that stakeholder input, we will maintain the existing six level Musculoskeletal Procedures APC structure for the CY 2019 OPPS. While we are not creating additional APC levels in this final rule with comment period, we reviewed the APC assignment of individual HCPCS codes that commenters requested be reassigned if additional APC levels were created to confirm whether their current assignment was appropriate. We believe that the APC assignment of CPT code 27279 (Arthrodesis sacroiliac joint) to APC 5116, and CPT codes 28740 (Fusion of foot bones) and 28297 (Correction hallux valgus) to APC 5114 remain appropriate based on their geometric mean costs.

With regards to the placement of the total knee arthroplasty procedure in APC 5115 (Level 5 Musculoskeletal Procedures), we continue to believe that C–APC 5115 is an appropriate APC assignment for the procedures described by CPT code 27447, which has an estimated geometric mean cost of $9,997.45. Further, we note that the 50th percentile IPPS payment for total knee arthroplasty procedures without major complications or comorbidities (MS–DRG 470) is approximately $11,550 for FY 2019. We note that the final CY 2019 payment for New Technology APC 1575 is $12,500.50. As previously stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 58394 through 59385), we would expect that beneficiaries selected for outpatient total knee arthroplasty procedures would generally be expected to be less complex than those treated as hospital inpatients. Therefore, we do not believe that it would be appropriate for the OPPS payment rate to exceed the IPPS payment rate for total knee arthroplasty procedures without major complications/comorbidities because IPPS cases would generally be expected to be more complicated and complex than those performed in the hospital outpatient setting.

We note that we rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare hospital cost reports appropriately (77 FR 68324). As we do every year, we will review and evaluate the APC groupings based on the latest available data in the next rulemaking cycle.

After consideration of the public comments we received, we are finalizing the six level Musculoskeletal Procedures APC structure. We also are finalizing the proposed assignments of the procedures described by CPT codes 27279 (Arthrodesis sacroiliac joint) to APC 5116, the procedures described by CPT codes 28740 (Fusion of foot bones) and 28297 (Correction hallux valgus) to APC 5114, and the procedures described by CPT code 27447 (Total knee arthroplasty) to APC 5115.

TABLE 31.—CY 2019 MUSCULOSKELETAL PROCEDURES APCs

APC	Group Title	HCPCS Codes Assigned to APC	APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	102	$227.04
5112	Level 2 Musculoskeletal Procedures	133	$1,324.69
5113	Level 3 Musculoskeletal Procedures	442	$2,646.02
5114	Level 4 Musculoskeletal Procedures	287	$5,748.86
5115	Level 5 Musculoskeletal Procedures	67	$10,806.47
5116	Level 6 Musculoskeletal Procedures	15	$15,535.58

16. Nasal Airway Obstruction Treatment (APC 5164)

For CY 2019, we proposed to continue to assign the procedures described by HCPCS code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s)) to APC 5164 (Level 4 ENT Procedures) with a proposed payment rate of approximately $2,241. We note that HCPCS code C9749 describes the Latera absorbable implant procedure for nasal airway obstruction.

Comment: One commenter disagreed with the proposed APC assignment of the procedure described by HCPCS code C9749 to APC 5164 and requested that CMS assign the procedure to New Technology APC 1523 (New Technology—Level 23 ($2,501–$3,000)), which had a proposed payment rate of approximately $2,751. The commenter stated that the cost for a pair of the Latera implants is $1,325, and that the proposed payment rate for APC 5164 does not cover the cost of performing the procedure. The commenter further stated that information from clinical experts and medical directors suggests that the complexity and resources to perform the Latera implant procedure are similar to those associated with procedures assigned to APC 5165 (Level 5 ENT Procedures).

Response: In December 2017, CMS received a New Technology APC application requesting a new HCPCS code for the Latera implant because, according to the applicant, the only available CPT code to report the procedure is CPT code 30999 (Unlisted procedure, nose). Based on our review of the application, assessment of the procedure, and input from our clinical advisors, we established HCPCS code C9749 effective April 1, 2018. For the April 2018 OPPS Update, we assigned HCPCS code C9749 to APC 5164 with a payment rate of approximately $2,199. We announced this new HCPCS code and APC assignment in the April 2018 OPPS quarterly update change request (Transmittal 4005, Change Request 10515, dated March 20, 2018). Based on cost information submitted to CMS in the New Technology APC application, we assigned the procedure to APC 5164 rather than New Technology APC 1523. However, based on further assessment on the nature of the procedure, and input from public commenters and our clinical advisors, we believe that HCPCS code C9749 should be reassigned to APC 5165 (Level 5 ENT Procedures) to more appropriately reflect the resource costs and clinical characteristics associated with the Latera implant procedure.

Therefore, after consideration of the public comment we received, we are finalizing our proposal, without modification, to assign the procedure described by HCPCS code C9749 from APC 5164 to APC 5165. The final payment rate for HCPCS code C9749 can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

17. Nerve Procedures and Services (APCs 5431 Through 5432)

For CY 2019, we proposed to continue the existing two-level structure of the Nerve Procedures APCs (APC 5431 through 5432), as displayed in Table 32 below and in Addendum A to the CY 2019 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

TABLE 32.—PROPOSED CY 2019 PAYMENT FOR NERVE PROCEDURES APCs

APC	Proposed CY 2019 OPPS Payment Rate
5431 (Level 1 Nerve Procedures)	$1,643.56
5432 (Level 2 Nerve Procedures)	$4,613.10

Comment: One commenter requested that CMS create a new modifier to identify the performance of continuous nerve block procedures that are performed as a secondary procedure, and to allow payment for the performance of such procedures, for example, the procedure described by CPT code 64416 (Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement)), not to be packaged if reported in combination with the procedure described by CPT code 29827 (Arthroscopy, shoulder, surgical; with rotator cuff repair). Instead, the commenter suggested a modifier to allow for payment at a full OPPS rate. The commenter noted that continuous nerve block procedure codes are assigned to status indicator ''T,'' which further provides that payment for the procedures are currently packaged when reported in combination with procedures that are assigned to C–APCs and, therefore, are not separately paid. The commenter stated that packaging payment for the certain procedures discourages hospitals from using non-opioid postsurgical pain alternative approaches, such as a continuous nerve block procedure.

The commenter further believed that CMS should create a new HCPCS code modifier in order to track, research, and identify the use of non-opioid pain management alternatives that are resulting in positive beneficiary health care impacts and outcomes, which are reducing opioid use and combatting the opioid crisis. Additionally, the commenter included a list of applicable continuous nerve block procedure codes (shown in the table below) to which the commenter suggested that a HCPCS modifier could be appended to indicate that the procedure would receive separate payment.

CPT Code	Long Descriptor
64416	Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement)
64446	Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement)
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter (including catheter placement)
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)
64463	Paravertebral block (pvb) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)
64487	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)
64489	Transversus abdominis plane (tap) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed)

Response: We appreciate the commenter's suggestion to create a new HCPCS modifier to identify the continuous nerve block procedures when performed as a secondary procedure, as well as recommending the list of CPT codes that should be considered for such inclusion for separate payment. However, payment for these continuous nerve block procedures is currently packaged under the OPPS because they are adjunctive to the primary service rendered and, therefore, represent components of a complete service. Therefore, at this time we will continue to package payment for these services, and consider the creation of a new HCPCS modifier and separate payment for such non-opioid alternatives approaches in future rulemaking.

Comment: One commenter suggested that CMS restructure the two-level Nerve Procedure APCs (APCs 5431 and 5432) to provide more payment granularity for the types of procedures included in the APCs by creating a third level. The commenter believed that there is a substantial payment differential between the procedures assigned to Level 1 Nerve Procedures APC 5431 and Level 2 Nerve Procedures APC 5432, and that the current payment for some of these procedures does not adequately cover the cost of providing the services. The commenter further stated that, as an example, the procedures described by CPT codes 64633 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint) and 64635 (destruction by neurolytic agent paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint), which are assigned to APC 5431 with a proposed payment rate of approximately $1,644, while the geometric means for each of the procedures described by CPT codes 64633 and 64635 are $1,482 and $1,729, respectively. The commenter recommended a potential geometric mean cost for a potential three-level APC structure within the Nerve Procedures APCs and submitted a three-level APC structure, along with estimated payment rates, which is shown in the table below.

APC Level	Number of Singles Used to Calculate APC Geometric Mean	Total Frequency of Claims	APC Geometric Mean Cost	Estimated Payment Rate	Number of HCPCS Codes	2 Times Rule Violation
5431	113,284	116,158	$1,583	$1,555	15	0
5432	15,035	17,051	$2,476	$2,431	58	0
5433	1,757	1,763	$5,373	$5,276	28	0

The commenter also recommended that CMS develop two new HCPCS G-codes to describe the performance of radiofrequency nerve ablation procedures. The commenter suggested that one of the G-codes could be created to describe procedures involving the genicular nerve, and the other G-code could be created to describe procedures

involving the sacroiliac joint. The commenter further recommended that both of these G-codes be created to describe procedures describing non-opioid treatment alternatives for chronic pain management, and to assign both of these newly created G-codes to Level 2 Nerve Procedures APC 5232 based on its recommended three-level APC structure, with an estimated payment rate of $2,431. The commenter was aware that Category I CPT codes are in development, but will not be ready for release until CY 2020 at the earliest. Therefore, the commenter requested that CMS create such G-codes in order to allow for physicians and hospitals to report the performance of the procedures and use of the approach, and to be paid for utilization of these procedures in the interim. The commenter supplied a suggested descriptor for the G-code for the genicular nerve as: *Radiofrequency nerve ablation; genicular nerves, including imaging guidance, when performed.* The commenter also supplied a suggested descriptor for the G-code for the sacroiliac joint as: *Radiofrequency never ablation; sacroiliac joint, including imaging guidance, when performed.*

Response: We appreciate the commenter's suggestions. However, at this time, we believe that the current two-level structure Nerve Procedures APCs provide an appropriate distinction between the resource costs at each level and clinical homogeneity. We will continue to review the APCs' structure to determine if additional granularity is necessary for this APC family in future rulemaking. In addition, we believe that more analysis of such groupings is necessary before adopting such change.

With regard to the request to establish new HCPCS G-codes, although new CPT codes are in development for release for the CY 2020 update, we note that it does not appear that a request for new temporary Category III codes was made for CY 2019. Nonetheless, we intend to take the commenter's request for new HCPCS G-codes under advisement.

Therefore, after consideration of the public comment received, we are finalizing our CY 2019 Nerve Procedures APCs two-level structure, as proposed. We refer readers to Addendum A to this final rule with comment period for the complete list of APCs and their payment rates. In addition, we refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. Both Addendum A and Addendum B are available via the internet on the CMS website.

18. Radiology and Procedures and Services

a. Imaging Procedures and Services (APCs 5521 Through 5524 and 5571 Through 5573)

Section 1833(t)(2)(G) of the Act requires the Secretary to create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those procedures that do not utilize contrast agents. In CY 2016, as a part of our comprehensive review of the structure of the APCs and procedure code assignments, we restructured the APCs that contain imaging services (80 FR 70392). The purpose of this restructuring was to more appropriately reflect the resource costs and clinical characteristics of the services classified within the Imaging APCs. The restructuring of the Imaging APCs resulted in broader groupings that removed the excessive granularity of grouping imaging services according to organ or physiologic system, which did not necessarily reflect either significant differences in resources or how these services are delivered in the hospital outpatient setting. In CY 2017, in response to public comments on the CY 2017 OPPS/ASC proposed rule, we further consolidated the Imaging APCs from 17 APCs in CY 2016 to 7 APCs in CY 2017 (81 FR 79633). These included four Imaging without Contrast APCs and three Imaging with Contrast APCs.

For CY 2018, we proposed to establish a new Level 5 Imaging without Contrast APC to more appropriately group certain imaging services with higher resource costs and stated that our latest claims data supported splitting the CY 2017 Level 4 Imaging without Contrast APC into two APCs such that the Level 4 Imaging without Contrast APC would include high frequency, low-cost services and the proposed Level 5 Imaging without Contrast APC would include low frequency, high-cost services. Therefore, for CY 2018, we proposed to add a fifth level within the Imaging without Contrast APCs (82 FR 33608). However, based on public comments, we did not finalize this proposal. In general, commenters disagreed with CMS' proposal to add a fifth level within the Imaging without Contrast APC series because they believed that the addition of a fifth level would reduce payment for several imaging services, including vascular ultrasound procedures (82 FR 59309 through 59311). Commenters also noted that the lower payment rates under the OPPS would also apply under the PFS.

For the CY 2019 OPPS/ASC proposed rule (83 FR 37096 through 37097), we reviewed the services assigned to the seven imaging APCs listed in Table 17 of the proposed rule. Specifically, we evaluated the resource costs and clinical coherence of the procedures associated with the four levels of Imaging without Contrast APCs and the three levels of Imaging with Contrast APCs, as well as identified for correction any 2 times rule violations, to the extent feasible. Based on the geometric mean cost for each APC, which was listed in Table 17 of the proposed rule, for CY 2019, we proposed to maintain the seven Imaging APCs, which consist of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs, and to make minor reassignments to the HCPCS codes within this series to resolve or mitigate any violations of the 2 times rule, or both.

We invited public comments on our proposal. Moreover, we specifically expressed an interest in receiving public comments and recommendations on the proposed HCPCS code reassignments associated with each of the seven Imaging APCs. We referred readers to Addendum B to the proposed rule (which is available via the internet on the CMS website) for the proposed list of specific codes that would be reassigned to each Imaging APC.

Comment: Commenters generally agreed with CMS' proposal to maintain the Imaging APCs: Four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs. The commenters stated that maintaining the current Imaging APC structure would provide more stability for these services and would allow for cost trends to be assessed over time. Several of these commenters believed that the cost data for the procedures within these APCs have been consistent for many years and cautioned CMS against changing payment for services assigned to these APCs. Commenters recommended that if CMS believes any revision to the current APCs is necessary, the revisions be considered for future rulemaking and be subject to review and comment from stakeholders, in order to continue to maintain stability and sufficient payment and in order for hospitals to be able to continue to provide these services.

Response: We appreciate the commenters' support for maintaining the seven Imaging APCs consisting of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs.

Comment: One commenter supported CMS' proposal to maintain the Level 3 Imaging with Contrast APC (APC 5573) as proposed for CY 2019. The commenter further stated that the

proposed payment rate for services in this APC appropriately reflects use of contrast agents and that a lower payment rate may lead to lower utilization of medically necessary contrast agents and may lead to use of more costly advanced imaging modalities such as cardiac MRI and nuclear perfusion studies, which will increase overall cost.

Response: As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37096 through 37097), we reviewed the resource costs and clinical coherence of the procedures associated with the four levels of Imaging without Contrast APCs and the three levels of Imaging with Contrast APCs, as well as reviewed any 2 times rule violations. Based on this review, we decided to maintain the seven Imaging APCs structure based on the clinical similarities and resource costs and in light of commenters' support of this proposal.

Comment: One commenter noted the lack of payment stability for the procedure described by CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2d), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography). The commenter noted that CMS proposed to reassign the procedure described by CPT code 93307 to APC 5523, and that, in CY 2018, this code was assigned to APC 5524. The commenter stated that the reassignment of CPT code 93307 to APC 5523 is inappropriate because it is not similar to the other procedures in that APC in regard to either clinical or resource use, and would result in a 52-percent decrease in payment for CY 2019 compared to the CY 2018 payment rate.

Response: We acknowledge the commenter's concern. However, we believe that the assignment of the procedure described by CPT code 93307 to APC 5523 is more appropriate based on clinical similarities and resource use. Specifically, we note that, based on the data available for this final rule with comment period, the lowest significant procedure geometric mean cost within APC 5523 is HCPCS code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time), with a geometric mean of $174.34, and the highest significant procedure cost within APC 5523 is HCPCS code 74455 (Urethrocystography, voiding, radiological supervision and interpretation), with a geometric mean cost of $358.11. The geometric mean cost of CPT 93307 is $352.15, which is similar to that of other procedures assigned to APC 5523.

Furthermore, the highest significant cost for a procedure within APC 5524 is for the procedure described by HCPCS 93312 (Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report), which has a geometric mean cost of $854.45. This proposed reassignment would have a greater impact on the 2 times violation by being over the violation limit by approximately $138, compared to the assignment of the CPT code to APC 5523, which also has a 2 times violation, but to a lesser extent (that is, approximately $31). Therefore, based on this information, we are finalizing the proposed structure of APC 5523, with assignment of the CPT codes as proposed in the CY 2019 OPPS/ASC proposed rule. We will continue to monitor clinical homogeneity and resource costs within these APCs to identify any payment changes that may be warranted in future rulemaking.

Comment: One commenter disagreed with the proposal to maintain the procedure described by HCPCS code G0297 (Low dose CT for lung cancer screening) in APC 5521 and believed the calculation of the geometric mean using the CT cost center does not sufficiently estimate costs, although CMS has 61,505 single claims to calculate the geometric mean cost for the procedure described by HCPCS code G0297. Based on its analysis, the commenter believed that using the diagnostic radiology cost center, which would result in estimated costs of $96.55 for the service, is more appropriate than the geometric mean cost of using the CT cost center, which is $37.96. The commenter believed that use of the CT cost centers is depressing payment for imaging services and believed all imaging studies should use the diagnostic radiology cost centers instead.

Response: We believe that the procedure described by HCPCS code G0297 is appropriately assigned to APC 5521, based on its estimated cost relative to that of the other procedures in the APC. We believe that the manner in which we establish the geometric mean for estimating service costs for the Imaging APCs is appropriate. As part of changes to establish more accurate cost reporting, we developed the CT, MRI, and Cardiac Catherization cost centers in the CMS 2552–10 form. Since the CY 2014 OPPS, in which we first included those cost centers for ratesetting, we have included a methodology that removes cost data from providers reporting the standard CT and MRI cost centers using ''square feet'' as the cost allocation statistic. We continue to believe this is appropriate as discussed in section II.A.1.b. of this final rule with comment period. However, we will continue to monitor payment for these imaging services and will consider the most appropriate methodology for ratesetting for such services in future rulemaking.

Additionally, we refer readers to the Medicare CY 2019 OPPS Final Rule Claims Accounting narrative for additional details regarding the calculation of the geometric mean costs.

Comment: One commenter expressed concern regarding payment stability for cardiac magnetic imaging with contrast services, specifically cardiac magnetic resonance imaging (MRI) for morphology with dye (the procedure described by CPT code 75561 within APC 5572). The commenter was concerned that the proposed payment for this service is set to decline by 15 percent from the CY 2018 payment rate and believed that this would threaten hospitals' ability to maintain equipment, supplies, and agents used for these services. The commenter requested that CMS continue to monitor payment for cardiac MR services, specifically the procedure described by CPT code 75561. The commenter suggested that CMS study how best to assign low volume procedures to an APC.

Response: Our analysis of the final rule updated claims data revealed a geometric mean cost of approximately $416.84 for CPT code 75561 based on 8,248 single claims out of 15,022 total claims. The geometric mean cost for APC 5572 is approximately $390. After reviewing the procedures assigned to APC 5572, we believe that the geometric mean cost for the procedure described by CPT code 75561 indicates that it is appropriately assigned to APC 5572 based on its clinical homogeneity and resource costs. As we do each year, we will continue to review the APC assignments for all services and items paid under the OPPS.

Comment: One commenter expressed concern regarding the payment amount for the procedure described by CPT code 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)) within APC 5571. Specifically, the commenter noted a 20-percent reduction from CY 2018 to CY 2019 within this APC. The commenter stated that the procedure described by

CPT code 75574 should be considered a low-volume service compared to other services within the APC and that high-volume codes within this APC are diluting the effect of the procedure described by CPT code 75574 on the APC payment rate. As a result, the commenter requested that CMS study how the APC structure could be modified to define low volume services and foster payment adequacy for low-volume codes such as CPT code 75574.

Response: We acknowledge the commenter's concerns regarding payment for CPT code 75574. At this point, we do not believe we have the necessary data to finalize a change based on the lack of information that the payment is insufficient. However, we will take under advisement and consider studying the impact of the APC structures on services that make up lower volume HCPCS and CPT codes in comparison to other services in higher volume HCPCS and CPT codes within an APC in future rulemaking. We remind hospitals that every year, we review the APC assignments for all services and items paid under the OPPS. We will reevaluate the APC assignment for the service described by CPT code 75574 for next year's rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to maintain the existing levels of the Imaging APCs, which consist of four levels of Imaging without Contrast APCs and three levels of Imaging with Contrast APCs. Table 33 below compares the CY 2018 and CY 2019 geometric mean costs for the imaging APCs. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reported under the OPPS. In addition, we refer readers to Addendum D1 to this final rule with comment period for the status indicator meanings for all codes reported under the OPPS. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

TABLE 33.—CY 2019 IMAGING APCs

CY 2019 APC	CY 2019 APC Title	CY 2018 APC Geometric Mean Cost	CY 2019 APC Geometric Mean Cost
5521	Level 1 Imaging without Contrast	$62.08	$62.84
5522	Level 2 Imaging without Contrast	$114.39	$113.48
5523	Level 3 Imaging without Contrast	$232.17	$232.56
5524	Level 4 Imaging without Contrast	$486.38	$501.79
5571	Level 1 Imaging with Contrast	$252.58	$203.48
5572	Level 2 Imaging with Contrast	$456.08	$389.22
5573	Level 3 Imaging with Contrast	$681.45	$697.73

b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5572)

As listed in Addendum B of the CY 2019 OPPS/ASC proposed rule, we proposed to continue to assign the procedure described by HCPCS code C9733 to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment rate of approximately $232. We also proposed to maintain the status indicator assignment of ''Q2'' (T-packaged) to indicate that payment for the service is conditionally packaged when performed in conjunction with other procedures on the same day but paid separately when performed as a stand-alone service.

Comment: One commenter stated that HCPCS code C9733 describes a procedure that includes disposable components and a contrast agent (indocyanine green) that cost hospitals approximately $455. Consequently, the commenter disagreed with the proposed APC assignment of this service to APC 5523 because the APC payment rate only covers 50 percent of the hospital costs for the procedure. In addition, the commenter believed that hospitals are underreporting the costs for the procedure described by HCPCS code C9733 based on its review of the CMS cost file which showed a geometric mean cost of $252.43, which is below the cost of the supplies associated with this procedure. The commenter suggested that hospitals may not be reporting this code when performed with an outpatient visit because payment for the service described by HCPCS code C9733 is conditionally packaged. Because of the perceived underreporting, the commenter requested that CMS provide instructions to hospitals in an upcoming MLN Matters article on appropriate billing for the procedure described by HCPCS code C9733.

Response: Based on our review of the CY 2019 final rule claims data, the procedure described by HCPCS code C9733 has a geometric mean cost of approximately $250 based on 173 single claims (out of 982 total claims). Because this procedure involves the use of a contrast agent, we believe that a reassignment to one of the existing Imaging with Contrast APCs would be more appropriate for HCPCS code C9733. Specifically, we believe that a reassignment to APC 5572 (Level 2 Imaging with Contrast), with a geometric mean cost of approximately $389 is appropriate. We believe this reassignment will improve clinical homogeneity and align the resource costs of the service described by HCPCS code C9733 with those of imaging with contrast procedures assigned to APC 5572.

In addition, with regard to the comment that hospitals underreport the procedure described by HCPCS code C9733, based on our analysis of the CY 2019 hospital outpatient claims data used for this final rule with comment period, we are unable to determine whether hospitals are underreporting the procedure. It is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. We rely on hospitals to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services on

claims and charges and costs for the services on their Medicare hospital cost report appropriately. However, we do not specify the methodologies that hospitals use to set charges for this or any other service. In addition, we state in Chapter 4 of the Medicare Claims Processing Manual that ''it is extremely important that hospitals report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions and correct coding principles, and all charges for all services they furnish, whether payment for the services is made separately paid or is packaged'' to enable CMS to establish future ratesetting for OPPS services.''

After consideration of the public comment received, we are finalizing our proposal with modification. Specifically, we are reassigning the procedure described by HCPCS code C9733 to APC 5572 instead of APC 5523, based on its clinical and resource homogeneity to the other procedures assigned to APC 5572. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

19. Remote Physiologic Monitoring (APCs 5012 and 5741)

As displayed in Table 34 below and in Addendum B to the CY 2019 OPPS/ASC proposed rule, we proposed to assign the procedure described by CPT code 99453 to APC 5012 (Clinic Visits and Related Services) with a proposed payment rate of approximately $116. We also proposed to assign the procedure described by CPT code 99454 to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment rate of approximately $37. The long descriptors for CPT codes 99453 and 99454 can be found in Table 34 below. The codes were listed as 990X0 and 990X1 (the 5-digit CMS placeholder codes), respectively, in Addendum B, with short descriptors, and in Addendum O, with long descriptors, to the CY 2019 OPPS/ASC proposed rule. We also assigned these codes to comment indicator ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2019 with proposed APC assignments, and that public comments would be accepted on their proposed APC assignments. We note that these codes will be effective January 1, 2019.

Comment: One commenter supported the APC assignments for both CPT codes 99453 and 99454 and requested that CMS finalize the APC assignments for CY 2019.

Response: We appreciate the commenter's support. Based on input from our medical advisors, we believe that procedures described by CPT codes 99453 and 99454 are appropriately assigned in APCs 5012 and 5741, respectively, based on clinical and resource homogeneity to the other services assigned to these APCs.

Therefore, after consideration of the public comment received, we are finalizing our proposal without modification for the procedures described by CPT codes 99453 and 99454. The final APC and status indicator assignments are listed in Table 34 below. The final payment rates for these codes, where applicable, can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 34.—PROPOSED AND FINAL CY 2019 APC AND SI ASSIGNMENTS FOR CPT CODES 99453 AND 99454

CY 2019 OPPS/ASC Proposed Rule 5-Digit CMS Placeholder Code	CY 2019 CPT Code	Long Descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC	Final CY 2019 SI	Final CY 2019 APC
990X0	99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	V	5012	V	5012
990X1	99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	Q1	5741	Q1	5741

20. Sclerotherapy (APC 5054)

As displayed in Table 35 below and in Addendum B of the CY 2019 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 36465 and 36466 to APC 5054 (Level 4 Skin Procedures), with a proposed payment rate of approximately $1,565.

Comment: One commenter disagreed with the proposed assignment of the procedures described by CPT codes 36465 and 36466 to APC 5054 and requested a reassignment to APC 5183 (Level 3 Vascular Procedures), which had a proposed payment rate of approximately $2,648. The commenter stated that the per-procedure cost for the Varithena foam sclerosant used in the procedure is $1,064. The commenter stated that APC 5183 is more clinically appropriate and reflects the resources required to perform the procedure. Specifically, the commenter indicated that the procedures described by CPT codes 36465 and 36466 share similar clinical and resource characteristics to the following surgical procedures that are assigned to APC 5183:

- CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated);
- CPT code 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated); and
- CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated).

Response: Based on input from our clinical advisors, we believe that the procedures described by CPT codes 36465 and 36466 are clinically similar to the procedures assigned to APC 5054. We do not believe that the resources used for the procedures described by CPT codes 36465 and 36466 are comparable to the procedures described by CPT codes 36473, 36475, and 36478, which are assigned to C–APC 5183. Consequently, we believe that APC 5054 appropriately reflects the resources and clinical characteristics associated with the procedures described by CPT codes 36465 and 36466. We note that the geometric mean cost for APC 5054 is approximately $1,562, which exceeds the cost of the Varithena foam sclerosant (as reported by the commenter) used in the procedure.

Therefore, after consideration of the public comment received, we are finalizing our proposal without modification for assignment of the procedures described by CPT codes 36465 and 36466 to APC 5054. The final APC and status indicator assignments are listed in Table 35 below. As we do every year, we review the APC assignments for all services and items paid under the OPPS. We will reassess the APC assignment for the procedures described by CPT codes 36465 and 36466 for the CY 2020 rulemaking. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 35.—PROPOSED AND FINAL CY 2019 APCs AND SI FOR CPT CODES 36465 AND 36466

CY 2019 CPT Code	Long Descriptor	Proposed CY 2019 SI	Proposed CY 2019 APC	Final CY 2019 SI	Final CY 2019 APC
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (*e.g.,* great saphenous vein, accessory saphenous vein)	T	5054	T	5054
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (*e.g.,* great saphenous vein, accessory saphenous vein), same leg	T	5054	T	5054

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments have been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the changes to the device pass-through payment policy. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are no device categories eligible for pass-through payment.

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at 42 CFR 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria: (1) If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA approval or clearance, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA approval or clearance is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability; (2) the device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and (3) the device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion. In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable costs of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoblation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or

devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Payment for CY 2019

We received seven applications by the March 1, 2018 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2019 OPPS/ASC proposed rule. We received four of the applications in the second quarter of 2017, one of the applications in the third quarter of 2017, and two of the applications in the first quarter of 2018. None of the seven applications were approved for device pass-through payment during the quarterly review process.

Applications received for the later deadlines for the remaining 2018 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2020 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*. A discussion of the seven applications received by the March 1, 2018 deadline is presented below, as detailed in the CY 2019 OPPS/ASC proposed rule (83 FR 37098 through 37107).

(1) AquaBeam System

PROCEPT BioRobotics Corporation submitted an application for a new device category for transitional pass-through payment status for the AquaBeam System. The AquaBeam System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The applicant stated that this is a very common condition typically occurring in elderly men. The clinical symptoms of this condition can include diminished urinary stream and partial urethral obstruction.[16] According to the applicant, the AquaBeam system resects the prostate to relieve symptoms of urethral compression. The resection is performed robotically using a high velocity, nonheated sterile saline water jet (in a procedure called Aquablation). The applicant stated that the AquaBeam System utilizes real-time intra-operative ultrasound guidance to allow the surgeon to precisely plan the surgical resection area of the prostate and then the system delivers Aquablation therapy to accurately resect the obstructive prostate tissue without the use of heat. The materials submitted by the applicant state that the AquaBeam System consists of a disposable, single-use handpiece as well as other components that are considered capital equipment.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the AquaBeam System is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted (either permanently or temporarily). The applicant also claimed the AquaBeam System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or items for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. However, in the CY 2000 interim final rule with comment period (65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment, not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 final rule with comment period (70 FR 68629 and 68630), we adopted as final our interpretation that surgical insertion or implantation criteria include devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We invited public comments on whether the AquaBeam System meets the eligibility criteria at § 419.66(b).

Comment: Commenters, including the manufacturer of AquaBeam and stakeholders, believed that the AquaBeam System met the eligibility criteria at § 419.66(b).

Response: We appreciate the commenters' input. However, we do not believe that the AquaBeam device meets

[16] Chungtai B. Forde JC. Thomas DDM et al. Benign Prostatic Hyperplasia. Nature Reviews Disease Primers 2 (2016) article 16031.

the eligibility criteria described at § 419.66(b). Specifically, we do not believe that the device is surgically implanted or inserted. As stated earlier, we have described in previous rulemaking (65 FR 67804 through 67805 and 70 FR 68329 through 68630) how we interpret the surgical insertion or implantation criteria, and we do not believe that the use of the Aquabeam device is consistent with that interpretation; namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted (70 FR 68630). Because we have determined that the AquaBeam device does not meet the basic eligibility criterion for transitional pass-through payment status, we have not evaluated this product to determine whether it meets the other criteria required for transitional pass-through payment for devices; that is the newness criterion, the substantial clinical improvement criterion, and the cost criterion.

After consideration of the public comments we received, we are not approving device pass-through payment status for the AquaBeam System for CY 2019.

(2) BioBag® (Larval Debridement Therapy in a Contained Dressing)

BioMonde US, LLC resubmitted an application for a new device pass-through category for the BioBag® (larval debridement therapy in a contained dressing), hereinafter referred to as the BioBag®. The application submitted contained similar information to the previous application received in March 2016 that was evaluated in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650). The only new information provided by the applicant were additional studies completed since the original application addressing the substantial clinical improvement criterion.

According to the applicant, the BioBag® is a biosurgical wound treatment (''maggot therapy'') consisting of disinfected, living larvae (Lucilia sericata) in a polyester net bag; the larvae remove dead tissue from wounds. The BioBag® is indicated for debridement of nonhealing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and nonhealing traumatic or postsurgical wounds. Debridement, which is the action of removing devitalized tissue and bacteria from a wound, is required to treat or prevent infection and to allow the wound to progress through the healing process. This system contains disinfected, living larvae that remove the dead tissue from wounds and leave healthy tissue undisturbed. The larvae are provided in a sterile polyester net bag, available in different sizes. The only other similar product is free-range (that is, uncontained) larvae. Free-range larvae are not widely used in the United States because application is time consuming, there is a fear of larvae escaping from the wound, and there are concerns about proper and safe handling of the larvae. The total number of treatment cycles depends on the characteristics of the wound, the response of the wound, and the aim of the therapy. Most ulcers are completely debrided within 1 to 6 treatment cycles.

With respect to the newness criterion at § 419.66(b)(1), the applicant received FDA clearance for the BioBag® through the premarket notification section 510(k) process on August 28, 2013, and the first U.S. sale of the BioBag® occurred in April 2015. The June 1, 2017 application is more than 3 years after FDA clearance but less than 3 years after its first U.S. sale. We invited public comments on whether the BioBag® meets the newness criterion.

Comment: The manufacturer stated that, although the BioBag® received its 510(k) clearance in 2013, BioBag® was not commercially available in the United States until its American-based production facility was established in 2015 to make the product available on the market.

Response: We appreciate the additional clarification from the manufacturer regarding the availability of the BioBag®. Based on this clarification, we have determined that BioBag® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant claimed that the BioBag® is an integral part of the wound debridement, is used for one patient only, comes in contact with human skin, and is applied in or on a wound. In addition, the applicant stated that the BioBag® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, or item for which depreciation and financing expenses are recovered. We also had determined in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79650) that the BioBag® is not a material or supply furnished incident to a service. We invited public comments on whether the BioBag® meets the eligibility criterion.

Comment: The manufacturer presented several reasons why the BioBag® is not a medical supply, but instead is a treatment for wound debridement, including the specialized nature of the product, that the product is not purchased in bulk, and that it provides a treatment outcome for non-healing wounds.

Response: We appreciate the additional information provided by the manufacturer to demonstrate that the BioBag® is not a material or medical supply. Based on this information, we have determined that the BioBag® meets the eligibility criterion.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes the BioBag®, the applicant suggested a category descriptor of ''Contained medicinal larvae for the debridement of necrotic non-healing skin and soft tissue wounds.'' We have not identified an existing pass-through payment category that describes the BioBag®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to the substantial clinical improvement criterion, the applicant provided substantial evidence that larval therapy may improve outcomes compared to other methods of wound debridement. However, given the existence of the Medical Maggots®, another form of larval therapy that has been on the market since 2004, the relevant comparison is between the BioBag® and the Medical Maggots®. There are many reasons to suspect that the BioBag® could improve outcomes and be preferable to the Medical Maggots®. In essence, with the latter, the maggots are directly placed on the wound, which may result in escape, leading to infection control issues as well as dosing variability. In addition, there are the issues with patient comfort. With the Biobag®, the maggots are in a sealed container so escape is not an issue. The applicant cited a study showing large decreases in maggot escape with the BioBag® as opposed to the Medical Maggots®. However, the applicant did

not provide any data that clinical outcomes are improved using the BioBag® as opposed to the Medical Maggots®. Based on the studies presented, we believe there are insufficient data to determine whether the BioBag® offers a substantial clinical improvement over other treatments for wound care. We invited public comments on whether the BioBag® meets the substantial clinical improvement criterion.

Comment: The manufacturer identified four items to indicate that the BioBag® may provide substantial clinical improvement over other available treatments. These items include debridement of wounds infected with MRSA, removing more tissue than loose maggots, the ease of use of the BioBag® over loose maggots, and less pain during debridement. The commenter stated that these items were supported by journal citations.

Several other commenters discussed the benefits of the BioBag®, and a few commenters discussed the benefits of larval debridement of wounds more generally. The commenters cited benefits that included that the BioBag® debrides only dead tissue, that BioBag® makes it easier to apply and remove maggots from wounds, and that BioBag® is a lower-cost and less-invasive treatment than surgical debridement. The commenters did not provide any support of these benefits by medical studies.

Response: We have reviewed these public comments and the additional journal citations and believe that most of the information provided by commenters reenforced our discussion in the proposed rule that stated that there are many reasons why the BioBag® may be preferable to treatment from loose maggots. However, we have not been provided with sufficient support from clinical studies to determine that the BioBag® meets the substantial clinical improvement criterion. Each of the three clinical studies cited by the manufacturer did identify possible benefits from the use of the BioBag® over treatment from loose maggots, hydrogel, or other surgical debridement methods. However, the findings had only marginal clinical significance, and did not reflect sufficient clinical support to reach the threshold of demonstrating significant clinical improvement.

For example, the study of debridement through containment,[17] was done *in vitro* (that is, in a laboratory setting) and not *in vivo* (that is, through testing on human subjects). Therefore, we are uncertain how the study findings would extrapolate to a patient receiving treatment. Second, we did not find that the clinical evidence fully supported the commenters' claimed benefits. For instance, a commenter, the manufacturer provided data comparing the amount of material debrided by the BioBag® at 4 days to free larvae at 3 days from the same study of debridement through containment.[18] To help demonstrate substantial clinical improvement, we believe that the commenter should have compared the amount of material debrided by both treatment methods over a similar time period. When similar time periods are compared between both treatment methods, the study found the amount of material debrided by the BioBag® and the free larvae is similar. In another study cited by the commenter discussing the prevalence of pain during maggot debridement therapy,[19] the share of study patients experiencing pain was similar for people receiving treatment using a BioBag® device when compared to people receiving maggot debridement therapy from free larvae kept in a cage-like dressing.

After consideration of the public comments we received, we have determined that the BioBag® does not meet the significant clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of a device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. With respect to the cost criterion, the applicant stated that the BioBag® would be reported with CPT code 97602 (Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (*e.g.,* wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session). CPT code 97602 is assigned to APC 5051 (Level 1 Skin Procedures), with a payment rate of $153.12, and a device offset of $0.02. The price of the BioBag® varies with the size of the bag ($375 to $435 per bag), and bag size selection is based on the size of the wound.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated reasonable cost of $435 for the BioBag® exceeds the applicable APC amount for the service related to the category of devices of $153.12 by 284.09 percent ($435/$153.12 × 100 = 284.09 percent). Thus, we determined that the BioBag® appears to meet the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of devices in the category must exceed the cost of the device-related portion of the APC payment amount by at least 25 percent, which means the device cost needs to be at least 125 percent of the device offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $435 for the BioBag® exceeds the proposed device-related portion of the APC amount for the related service of $0.02 by 2,175,000 percent ($435/$0.02 × 100 = 2,175,000 percent). Thus, we determined that the BioBag® appears to meet the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device exceeds 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $435 for the BioBag® and the portion of the proposed APC payment for the device of $0.02 exceeds 10 percent at 284.08 percent (($435 − $0.02)/$153.12 × 100 = 284.08 percent). Thus, we determined that the BioBag® appears to meet the third cost significance test and satisfies the cost significance criterion. We invited public comments on whether the BioBag® meets the device pass-through payment criteria discussed in this section, including all three cost criteria.

We did not receive any public comments on the cost criteria for the BioBag®. Therefore, we have determined that the BioBag® does meet all three cost criteria.

After consideration of the public comments we received and our review of the criteria necessary to receive device pass-through payment, we are not approving the application for the BioBag® to receive device pass-through payment status in CY 2019 because the BioBag® does not meet the substantial clinical improvement criterion.

[17] Blake, F. et al. The biosurgical wound debridement: Experimental investigation of efficiency and practicability. Wound Rep Reg, 2007: 15; 756–761. 3.

[18] Ibid. Blake, F. et al.

[19] Mumcuoglu, K. et al. Pain related to maggot debridement therapy. *J Wound Care.* 2012;21(8): 400–405.

(3) BlastX™ Antimicrobial Wound Gel

Next Science™ has submitted an application for a new device category for transitional pass-through payment status for BlastX™. According to the manufacturer, BlastX™ is a PEG-based aqueous hydrogel which contains citric acid, sodium citrate, and benzalkonium chloride, buffered to a pH of 4.0 at 2.33 osmolarity. BlastX™ received a 510(k) clearance from the FDA on March 6, 2017. BlastX™ is indicated for the management of wounds such as Stage I–IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, postsurgical wounds, first and second degree burns, and grafted and donor sites.

The manufacturer stated in its application for transitional pass-through payment status that BlastX™ works by disrupting the biofilm matrix in a wound and eliminating the bacteria absorbed within the gel. The manufacturer asserted that disrupting and eliminating the biofilm removes a major barrier to wound healing. The manufacturer also asserted that BlastX™ is not harmful to host tissue and stated that BlastX™ is applied to the wound every other day as a thin layer throughout the entire wound healing process. When used as an adjunct to debridement, BlastX™ is applied immediately after debridement to eliminate any remaining biofilm and prevent the growth of new biofilm.

Based on the evidence provided in the manufacturer's application, BlastX™ is not a skin substitute and cannot be considered for transitional pass-through payment status as a device. To be considered a device for purposes of the medical device pass-through payment process under the OPPS, a skin substitute needs to be applied in or on a wound or other skin lesion based on 42 CFR 419.66(b)(3). It should be a product that is primarily used in conjunction with the skin graft procedures described by CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (78 FR 74937). The skin substitute should only be applied a few times during a typical treatment episode. BlastX™, according to the manufacturer, may be used in many other procedures other than skin graft procedures, including several debridement and active wound care management procedures. The manufacturer also stated that BlastX™ would be used in association with any currently available skin substitute product and that the product should be applied every other day, which is not how skin substitute products for skin graft procedures are used to heal wounds. BlastX™ is not a required component of the skin graft service, and is used as a supply that may assist with the wound healing process that occurs primarily because of the use of a sheet skin substitute product in a skin graft procedure.

Therefore, with respect to the eligibility criterion at § 419.66(b)(3), in the proposed rule, we determined that BlastX™ is not integral to the service provided (which is a skin graft procedure using a sheet skin substitute), is a material or supply furnished incidentally to a service, and is not surgically inserted into a patient. BlastX™ does not meet the eligibility criterion to be considered a device for transitional pass-through payment. Therefore, we did not evaluate the product on the other criteria required for transitional pass-through payment for devices, including the newness criterion, the substantial clinical improvement criterion, and the cost criterion. We invited public comments on the eligibility of BlastX™ for transitional pass-through payment for devices.

We did not receive any public comments regarding the eligibility of BlastX™ for transitional pass-through payment for devices. Therefore, we are not approving BlastX™ for transitional pass-through payment status for CY 2019 because the product does not meet the eligibility criterion to be considered a device.

(4) EpiCord®

MiMedx® submitted an application for a new OPPS device category for transitional pass-through payment status for EpiCord®, a skin substitute product. According to the applicant, EpiCord® is a minimally manipulated, dehydrated, devitalized cellular umbilical cord allograft for homologous use that provides a protective environment for the healing process. According to the applicant, EpiCord® is comprised of the protective elements of the umbilical cord with a thin amnion layer and a thicker Wharton's Jelly mucopolysaccharides component. The Wharton's Jelly contains collagen, hyaluronic acid, and chondroitin sulfate, which are the components principally responsible for its mechanical properties.

The applicant stated that EpiCord® is packaged as an individual unit in two sizes, 2 cm x 3 cm and 3 cm x 5 cm. The applicant asserted that EpiCord® is clinically superior to other skin substitutes because it is much thicker than dehydrated amnion/chorion allografts, which allows for application over exposed bone, tendon, nerves, muscle, joint capsule and hardware. According to the applicant, due to its unique thicker, stiffer structure, clinicians are able to apply or suture EpiCord® for deep, tunneling wounds where other products cannot fill the entire wound bed or dead spaces.

With respect to the newness criterion at § 419.66(b)(1), EpiCord® was added to the MiMedx® registration for human cells, tissues, and cellular and tissue-based products (HCT/Ps) on December 31, 2015. In adding EpiCord, MiMedx® asserted that EpiCord® conformed to the requirements for HCT/Ps regulated solely under section 361 of the Public Health Service Act and the regulations at 21 CFR part 1271. For these products, FDA requires that the manufacturer register and list its HCT/Ps with the FDA's Center for Biologics Evaluation and Research (CBER) within 5 days after beginning operations and update its registration annually, and MiMedx® provided documentation verifying that EpiCord® had been registered. However, no documentation regarding an FDA determination that EpiCord® is appropriate for regulation solely under section 361 of the Public Health Service Act had been submitted. According to the applicant, December 31, 2015 was the first date of sale within the United States for EpiCord®. Therefore, it appears that market availability of EpiCord® is within 3 years of this application.

We note that a product that is regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271, as asserted by the manufacturer of Epicord®, is not regulated as a device under the Federal Food, Drug, and Cosmetic Act. The regulations at 21 CFR 1271.20 state that ''If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a) [for regulation solely under section 361 of the Public Health Service Act and the regulations in part 1271], and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product. . . .'' The Federal Food, Drug, and Cosmetic Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from FDA before they may offer them for sale in the United States. We did not receive documentation from the applicant that EpiCord® is regulated as a device by FDA in accordance with Medicare regulations at 42 CFR 419.66(b)(1). We invited public comments on whether EpiCord® meets the newness criterion.

Comment: The manufacturer believed that EpiCord® meets the newness criterion. The manufacturer stated that HCT/P products are regulated by the FDA through a registration process and have been paid by CMS for many years under the current regulatory structure. The manufacturer believed the newness criterion requirement for FDA approval for a product should only apply when FDA approval is required for that product. The manufacturer stated that FDA approval does not apply to EpiCord® because of its HCT/P status. The manufacturer stated that the pass-through payment application for EpiCord® was submitted within 3 years of EpiCord® being introduced onto the U.S. market. Finally, the manufacturer noted that the Medicare statute requires that biologicals be included in the category of products that can be considered for pass-through payment status and stated that, if HCT/Ps cannot be considered for transitional pass-through payment through the device pathway, the HCT/P products should be returned to the drug and biological transitional pass-through pathway.

Response: To be able to determine whether a product meets the newness criterion, we need to determine a date when a product could first be used in the United States. Generally, we use the FDA clearance or approval date. We also have a provision in the newness criterion to use the date of first United States sale of the product rather than the FDA approval date, to accommodate the rare cases where a device receives FDA approval but the manufacturer experiences a significant delay establishing a manufacturing and distribution capacity for the new device. We agree that FDA approval cannot be required to be used for the newness criterion when there is no requirement for a new product to receive FDA approval. However, we still need some means to determine whether a product has been able for use in the United States for 3 years or less. The best alternative that we can identify to establish the date a product is considered new is to rely on registration to the FDA HCT/P registry, which indicates the existence of a new product.

Comment: One commenter did not believe that EpiCord® meets the newness criterion. The commenter asserted that EpiCord® is considered to be the same product as EpiFix® that was introduced onto the U.S. market in 2011, and that the application for pass-through payment status for EpiCord® was submitted after the 3-year timeframe for a new product to apply for pass-through payment status. The commenter cited a HCPCS Workgroup decision in 2016 that assigned the use of EpiCord® to HCPCS code Q4131, which, until December 31, 2018, was the identifying HCPCS code for the use of EpiFix®. The commenter also asserted that EpiFix® may also receive pass-through payments, which the commenter believed should not occur, because it will be difficult to determine whether HCPCS code Q4131 is being billed for the use of EpiFix® or EpiCord®.

Response: We disagree with the commenter's assertion that EpiFix® and EpiCord® are the same product. On December 31, 2015, MiMedx, the manufacturer of EpiCord®, submitted a filing to the FDA HCT/P registry representing EpiCord® as a new product that is a separate product from EpiFix®. In addition, the HCPCS Workgroup has made a decision, effective on January 1, 2019, to designate separate HCPCS codes for EpiFix® (Q4186) and EpiCord® (Q4187) that also demonstrates EpiCord® is a separate product from EpiFix®. We believe that EpiCord® is a separate product from EpiFix®.

After consideration of the public comments we received, we have determined that EpiCord® meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, EpiCord® is a skin substitute product that is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted into the patient. The applicant also claimed EpiCord® meets the device eligibility requirements of § 419.66(b)(4) because EpiCord® is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material. We invited public comments on whether EpiCord® meets these eligibility criteria.

We did not receive any public comments regarding whether EpiCord® meets the eligibility criterion. Based on the information we have received, we have determined that EpiCord® meets the eligibility criterion.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through category that describes EpiCord®. There are no present or previously established device categories for pass-through status that describe minimally manipulated, lyophilized, nonviable cellular umbilical membrane allografts regulated solely under section 361 of the Public Health Service Act and the regulations at 21 CFR part 1271. MiMedx® suggested a new device category descriptor of ''Dehydrated Human Umbilical Cord Allografts'' for EpiCord®.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With regard to the substantial clinical improvement criterion, the applicant asserted that EpiCord® reduces the mortality rate with use of the device; reduces the rate of device-related complications; decreases the rate of subsequent diagnostic or therapeutic interventions; decreases the number of future hospitalizations or physician visits; provides more rapid beneficial resolution of the disease process treated because of the use of the device; decreases pain, bleeding, or other quantifiable symptom; and reduces recovery time.

To determine if the product meets the substantial improvement criterion, we compared EpiCord® to other skin substitute products. Compared to NEOX CORD 1K Wound Allograft, EpiCord® has half the levels of Vascular Endothelial Growth Factor (VEGF) and insulin-like growth factor binding protein-4 (IGFBP–4) and lower levels of Glial Cell Line Derived Neurotrophic Factor (GDNF) and Epidermal Growth Factor (EGF). Despite EpiCord® having higher levels of other growth factors, the cumulative effect of these differences has not been sufficiently demonstrated in the application. Moreover, most professional opinions do not compare EpiCord® to specific alternative skin substitutes; the few that do are, for the most part, of limited specificity (in terms of foci of superiority to other skin substitutes). Studies demonstrated 41 percent higher relative rates (4.1 percent higher absolute rates) of severe complications for EpiCord® compared to standard of care. Additionally, the control group was moist dressings and offloading (instead of another umbilical or biologic product). Furthermore, 38 percent of EpiCord® patients in the study were smokers versus 58 percent of

control patients (smoking impairs wound healing; thus, this important dissimilarity between intervention and study populations casts doubt on attributing observed benefit to the intervention).

Based on the evidence submitted with the application, we had insufficient evidence that EpiCord® provides a substantial clinical improvement over other treatments for wound care. We invited public comments on whether EpiCord® meets the substantial clinical improvement criterion.

Comment: The manufacturer responded to several statements regarding EpiCord® and substantial clinical improvement in the CY 2019 OPPS/ASC proposed rule. The analysis in the proposal rule noted that the pass-through application for EpiCord® stated that EpiCord® had higher levels of some growth factors and lower levels of other growth factors than NEOX CORD 1K Allograft. However the original application did not clarify what the overall effect the differences in growth factors had on the effectiveness of EpiCord® for wound care and the proposed rule text expressed concern regarding comparisons to individual skin substitute products. The manufacturer asserted that the findings in the application, which were updated by the manufacturer, show that the combination of growth factors and proteins working together does improve wound healing in a complex environment. Also, the manufacturer stated that EpiCord® is the only umbilical cord wound product with a published multi-center, prospective, randomized-controlled, comparative parallel study.

The manufacturer responded to a statement in the proposed rule that noted 41 percent higher relative rates of severe complications for EpiCord® compared to the standard of care, and concerns the control group in the studies were moist dressings and offloading instead of a biologic product. The manufacturer indicated that the studies include adverse events from all causes and a new study in progress will show no adverse events directly related to EpiCord® or alginate dressings. The manufacturer also stated that many wound experts do not attempt to compare new products to each other because of the high variability of the composition of products, how they are applied, and the dynamics of how different products work.

The manufacturer replied to a statement in the CY 2019 OPPS/ASC proposed rule questioning the substantial higher amount of smokers in the control group for the primary study compared to the group of EpiCord® patients. The manufacturer noted that the concern is that smoking impairs wound healing, and the presence of a higher number of smokers in the control group casts doubt on the conclusion that the difference in outcomes between the control group and the EpiCord® group was because of the use of EpiCord®. The manufacturer performed statistical analyses and the manufacturer reported that it found the effect of the higher proportion of smokers in the control group was not statistically significant.

Finally, the manufacturer asserted that EpiCord® meets the substantial clinical improvement criterion as a result of the published multi-center randomized controlled study showing an 81-percent healing rate within 12 weeks, which increases to a 96-percent healing rate when adequate debridement is performed.

Response: We appreciate the detailed response to the questions we had regarding the study the manufacturer submitted as evidence that EpiCord® would have substantial clinical improvement over comparable wound care treatments. However, this study on its own is not sufficient to establish substantial clinical improvement. First, independent replication of the findings of the study has not been performed. The study indicates beneficial effects from the use of EpiCord®; however, it is not clear if the findings can be reproduced. Multiple studies with similar conditions, and a more equitable distribution of smokers in the control and intervention groups, would be a first step to determine if the findings are valid. Second, more comparisons need to be done with different classes of biological skin substitute products. Given the number of skin substitute products on the U.S. market, it is not possible to compare EpiCord® to each product. However, we believe that studies comparing the product against products made with epithelial tissue, other human-sourced products, and animal-sourced products could provide more evidence demonstrating the clinical superiority of EpiCord®.

Comment: Multiple commenters supported granting EpiCord® transitional pass-through payment status. Many of the commenters discussed the strength of the structure of EpiCord®, the high levels of human growth factors found in the product, and its ability to heal complex wounds, but did not provide support by studies or other clinical research.

Response: We appreciate the additional information that the commenters provided on the performance and the benefits of EpiCord®. However, many skin substitute products can be used to heal complex wounds. In addition, none of the commenters provided clinical evidence of how the high levels of human growth factors led to EpiCord® having a superior performance to other skin substitute products.

After consideration of the public comments we received, we have determined that EpiCord® does not meet the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. EpiCord® would be reported with CPT code 15271 or 15275. CPT code 15271 describes the application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area. CPT code 15275 describes the application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area. Both codes are assigned to APC 5054 (Level 4 Skin Procedures). CPT codes 15271 through 15278 are assigned to either APC 5054 (Level 4 Skin Procedures), with a payment rate of $1,427.77 and a device offset of $4.70, or APC 5055 (Level 5 Skin Procedures), with a payment rate of $2,504.69 and a device offset of $35.01. The price of EpiCord® is $1,595 for the 2 cm x 3 cm and $3,695 for the 3 cm x 5 cm product size.

To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $3,695 for the 3 cm x 5 cm product exceeds the applicable APC amount for the service related to the category of devices of $1,427.77 by 258.80 percent ($3,695/$1427.77 × 100 percent = 258.80 percent). Therefore, it appears that EpiCord® meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the

devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $3,695 for the 3 cm x 5 cm product exceeds the device-related portion of the APC payment amount for the related service of $4.70 by 78,617.02 percent ($3,695/$4.70 × 100 percent = 78,617.02 percent). Therefore, it appears that EpiCord® meets the second cost significance test.

Section 419.66(d)(3), the third cost significance test, requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $3,695 for the 3 cm x 5 cm product and the portion of the APC payment amount for the device of $4.70 exceeds 10 percent at 258.47 percent (($3,695 − $4.70)/$1,427.77) × 100 percent = 258.47 percent). Therefore, it appears that EpiCord® meets the third cost significance test. Based on the costs submitted by the applicant and the calculations noted earlier, it appears that EpiCord® meets the cost criterion at § 419.66(c)(3) for new device categories. We invited public comments on whether EpiCord® meets the cost criterion for device pass-through payment.

We did not receive any public comments regarding the cost criteria for EpiCord®. Based on the information that we received, we have determined that EpiCord® meets the cost criteria.

After consideration of the public comments and additional information we have received, we are not approving EpiCord® for transition pass-through payment status in CY 2019 because the product does not meet the substantial clinical improvement criterion.

(5) remedē® System Transvenous Neurostimulator

Respicardia, Inc. submitted an application for a new device category for transitional pass-through payment status for the remedē® System Transvenous Neurostimulator. According to the applicant, the remedē® System is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients. The applicant stated that the remedē® System is the first and only implantable neurostimulator to use transvenous sensing and stimulation technology. The applicant also stated that the remedē® System consists of an implantable pulse generator, a transvenous lead to stimulate the phrenic nerve and a transvenous sensing lead to sense respiration via transthoracic impedance. Lastly, the applicant stated that the device stimulates a nerve located in the chest (phrenic nerve) that is responsible for sending signals to the diaphragm to stimulate breathing to restore normal sleep and respiration in patients with moderate to severe central sleep apnea (CSA).

With respect to the newness criterion at § 419.66(b)(1), the applicant received a Category B Investigational Device Exemption (IDE) from FDA on April 18, 2013. Subsequently, the applicant received approval of its premarket approval (PMA) application from FDA on October 6, 2017. The application for a new device category for transitional pass-through payment status for the remedē® System was received on May 31, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the remedē® System meets the newness criterion.

Comment: The manufacturer believed that that the remedē® System meets the newness criterion.

Response: We appreciate the commenter's input.

After consideration of the public comments we received, we believe that the remedē® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the remedē® System is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed the remedē® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the remedē® System. The applicant proposed a category descriptor for the remedē® System of ''generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation.'' We invited public comments on this issue.

Comment: The manufacturer of the device indicated that there is no an existing pass-through payment category that describes the remedē® System.

Response: We appreciate the manufacturer's input.

After consideration of the public comments we received, we believe that the remedē® System meets the eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant submitted several journal articles that discussed the health effects of central sleep apnea (CSA) which include fatigue, decreased mental acuity, myocardial ischemia, and dysrhythmias. The applicant stated that patients with CSA may suffer from poor clinical outcomes, including myocardial infarction and congestive heart failure.[20]

The applicant claims that the remedē® System has been found to significantly improve apnea-hypopnea index (AHI), which is an index used to indicate the severity of sleep apnea. AHI is represented by the number of apnea and hypopnea events per hour of sleep and was used as the primary effectiveness endpoint in the remedē® System pivotal trial. The applicant noted that the remedē® System was shown to improve AHI in small, self-controlled studies as well as in larger trials.

The applicant reported that in the pivotal study, a large, multicenter, randomized controlled trial of CSA patients, intention-to-treat analysis found that 51 percent (35/68) of CSA patients using the remedē® System had greater than 50 percent reduction of apnea-hypopnea index (AHI) from baseline at 6 months compared to 11 percent (8/73) of the control group ($p<0.0001$). Per-protocol analysis found that 60 percent (35/58) of remedē® System patients had a greater than 50

[20] Costanzo, M.R., et al., Mechanisms and Clinical Consequences of Untreated Central Sleep Apnea in Heart Failure. *Journal of the American College of Cardiology,* 2015. 65(1): p. 72–84.

percent reduction of AHI and in 74 percent (26/35) of these patients AHI dropped to <20.[21]

According to the applicant, an exploratory post-hoc analysis of patients with CSA and congestive heart failure (CHF) in the Pivotal trial found that, at 6 months, the remedē® System group had a greater percentage of patients with >=50 percent reduction in AHI compared to control group (63 percent versus 4 percent, p< 0.001).[22]

The applicant noted that patient symptoms and quality of life were improved with the remedē® System therapy. The mean Epworth Sleepiness Scale (ESS) score significantly decreased in remedē® System patients, indicating less daytime sleepiness.[23]

Adverse events associated with remedē® System insertion and therapy included lead dislodgement/dislocation, hematoma, migraine, atypical chest pain, pocket perforation, pocket infection, extra-respiratory stimulation, concomitant device interaction, and elevated transaminases.[24] There were no patient deaths that were related to the device implantation or therapy.

One concern regarding the remedē® System is the potential for complications in patients with coexisting cardiac devices, such as pacemakers or ICDs, given that the remedē® System device requires lead placement and generation of electric impulses. Another concern with the evidence of substantial clinical improvement is that there is limited long-term data on patients with remedē® System implants. The pivotal trial included only 6 months of follow-up. Also, while the applicant reported a reduction in AHI in the treatment group, the applicant did not establish that that level of change was biologically meaningful in the population(s) being studied. The applicant did not conduct a power analysis to determine the necessary size of the study population and the necessary duration of the study to detect both early and late events.

In addition, patients in the pivotal study were not characterized by the use of cardiac devices. Cardiac resynchronization therapy (CRT), in particular, is known to improve chronic sleep apnea in addition to its primary effects on heart failure, and central apnea is a marker of the severity of the congestive heart failure. The applicant did not conduct subset analyses to assess the impact of cardiac resynchronization therapy.

Lastly, while evaluation of AHI and quality of life metrics show improvement with the remedē® System, the translation of those effects to mortality benefit is yet to be determined. Further studies of the remedē® System are likely needed to determine long-term effects of the device, and as well as its efficacy compared to existing treatments of CPAP or medications.

Based on the evidence submitted with the application, we had insufficient evidence that the remedē® System provides a substantial clinical improvement over other similar products and invited public comments on whether the remedē® System meets the substantial clinical improvement criterion.

Comment: The manufacturer of the remedē® System believed that this device meets the substantial clinical improvement criterion and provided additional data to support this assertion. The manufacturer noted that the primary endpoint of the pivotal study was a reduction of at least 50 percent in the apnea-hyponea index that is used to classify apnea severity and has been used as a common endpoint in predicate studies testing apnea therapy in sleep literature. The manufacturer further indicated that the remedē® System significantly improves secondary endpoints. Patients had improved oxygenation, reduced hypoxia, and 79 percent of treatment group subjects reported improved quality of life as assessed through the Patient Global Assessment. The manufacturer asserted that the study cited was the first randomized study in central sleep apnea to demonstrate improvements in REM sleep and arousals. Further, the manufacturer noted that the treatment group experienced a 3.7 percentage point improvement in the Epworth sleepiness scale, meaning these patients were less sleepy than the control group. The manufacturer indicated, in response to CMS' questions, that its clinical trials were not designed to establish a clinical improvement in mortality from this device. However, the manufacturer asserted that post-trial analysis indicated some improvement in left ventricular ejection fraction, which is associated with reduced mortality, and increased time to first hospitalization for New York Heart Association heart failure patients with reduced ejection fraction. The manufacturer also indicated that reductions in the Apnea Hypopnea Index for trial participants that received the remedē® System was now greater at 12 months than it was at 6 months.

In response to CMS' question regarding why an untreated control group was used in the pivotal trial, as opposed to a direct comparison with CPAP or other treatments, the manufacturer presented several reasons, such as considerable controversy about CPAP in CSA patients with heart failure due to CPAP patients with an ejection fraction less than 40 percent having higher mortality, and a dearth of prospective, randomized clinical data on the safety and efficacy of using CPAP, ASV, or medications to treat patients with non-heart failure CSA.

Regarding CMS' question of why no power analysis was performed to determine the necessary size of the study population and the necessary duration of the study to detect both early and late events, the manufacturer noted that it worked directly with clinical experts and consulted with the FDA in designing the clinical trial, which the manufacturer maintains was effective and well-rounded. The manufacturer noted that the rationale was that the remedē® System would be evaluated on a continuum of efficacy versus safety, but noted that had they determined to power the study for a primary safety endpoint based on the threshold of other implantable cardiac devices, the pivotal trial would have been adequately powered based on the study design (132 patients needed versus 151 enrolled).

In response to CMS' question regarding potential complications in patients with coexisting cardiac devices, the manufacturer noted that it was understood that many CSA patients would likely have other cardiac devices already implanted and that this led to the design of both implant and testing procedures that accommodated concomitant devices. The manufacturer noted that the remedē® System is typically placed on the right side of the chest to leave room for patients to have a cardiac device, which are typically placed on the left side, and that, in the pivotal trial, implantation of the remedē® System in patients with a concomitant device did not demonstrate any increased risk. Further, the manufacturer noted that key metrics of implant duration, use of contrast dye, and fluoroscopy time were similar between patients with and without a

[21] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

[22] Goldberg, L.R., et al. (2017). In Heart Failure Patients with CSA, Stimulation of the Phrenic Nerve Improves Sleep and Quality of Life. *Journal of Cardiac Failure, 23(8):* p. S15.

[23] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

[24] Costanzo, M.R., et al. (2016). Transvenous neurostimulation for central sleep apnoea: a randomised controlled trial. *The Lancet, 388(10048):* p. 974–982.

concomitant cardiac device. Regarding specific study results, the manufacturer noted that 42 percent (64 of 151) of patients in the pivotal trial had a concomitant device and 98 percent (63 of 64) of patients with a concomitant cardiac device were successfully implanted, as compared to 96 percent (81 of 84) of patients with no concomitant device. The manufacturer believed that there is no increased risk at the time of implant for patients with a coexisting cardiac device. With regard to safety post-procedure, the commenter noted there was no difference in related SAEs between the groups with and without a concomitant cardiac device.

Regarding CMS' question about whether the impact of cardiac resynchronization therapy (CRT) drove improvement for heart failure patient with a concomitant CRT device, the manufacturer noted limited literature available on this topic, but stated that the literature that does exist suggests that CRT may improve the apnea hypopnea index in some patients, which may be due to an improvement in ejection fraction. However, the manufacturer noted that all CRT patients in the remedē® System pivotal trial had their CRT devices for a minimum of nine months and that despite having CRT for a significant duration, still had severe CSA at baseline. Accordingly, the manufacturer believed that it is unlikely that significant CSA improvements were based on CRT rather than the remedē® System. The manufacturer noted that statistically significant subgroup analysis on CRT was difficult, but believed that the CRT subgroup did not lead to the overall results on the primary endpoint because the CRT subgroup ''underperformed'' relative to the non-CRT subgroup.

Finally, with respect to CMS' question regarding whether the clinical results and patient response were durable and sustainable over time, the manufacturer asserted that it continues to collect effectiveness data beyond the 6-month endpoints of the pivotal IDE trial and that 12-month follow-up results on the pivotal IDE trial were recently published, demonstrating a trend towards increasing benefit for the treatment group at 12 months. Specifically, the commenter stated that, at 12 months, 91 percent of patients saw a reduction of AHI and with 67 percent achieving a 50 percent or greater reduction in AHI (compared to 60 percent at 6 months).

Several commenters, individual physicians who have treated CSA patients with the remedē® System, stated that, for these patients, traditional types of positive pressure ventilation did not work and the remedē® System is the only treatment available.

Response: We appreciate the commenters' input. After reviewing the additional information provided during the public comment period, we agree that the remedē® System has been shown to improve patients symptoms of central sleep apnea, improve quality of life, requires minimal patient compliance compared to other treatments, and has a low adverse event profile. However, with regard to our questions about impacts on mortality, the applicant did note that its studies were not powered to demonstrate a mortality benefit.

Commenters have adequately addressed the clinical concerns that we outlined in the proposed rule with additional evidence, longer follow-up from the pivotal IDE trial, the interplay of the remedē® System and a concomitant cardiac device, and information about power calculations and other data summarized above. Further, we believe that the remedē® System offers a treatment option for a patient population unresponsive to, or ineligible for, treatment involving currently available options. That is, those patients who have been diagnosed with moderate to severe CSA have no other available treatment options than the remedē® System. Accordingly, we have determined that the remedē® System has demonstrated substantial clinical improvement relative to existing treatment options for patients diagnosed with moderate to severe CSA.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the remedē® System would be reported with CPT code 0424T. CPT code 0424T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which had a CY 2017 payment rate of $27,047.11 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0424T had a device offset amount of $11,089 at the time the application was received. According to the applicant, the cost of the remedē® System was $34,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $34,500 for the remedē® System exceeds 127 percent of the applicable APC payment amount for the service related to the category of devices of $27,047.11 ($34,500/$27,047.11 × 100 = 127.5 percent). Therefore, we believe the remedē® System meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $34,500 for the remedē® System exceeds the cost of the device-related portion of the proposed APC payment amount for the related service of $11,089 by 311 percent ($34,500 − $11,089) × 100 = 311 percent). Therefore, we believe that the remedē® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $34,500 for the remedē® System and the portion of the proposed APC payment amount for the device of $11,089 exceeds the APC payment amount for the related service of $27,047.11 by 87 percent (($34,500/11,089)/$27,047.11 × 100 = 86.6 percent). Therefore, we believe that the remedē® System meets the third cost significance test.

We invited public comments on whether the remedē® System meets the device pass-through payment criteria discussed in this section, including the cost criteria for device pass-through payment.

Comment: The manufacturer of the remedē® System believed that the remedē® System meets the cost criterion for device pass-through payment status.

Response: We appreciate the manufacturer's input.

After consideration of the public comments we received, we are approving the remedē® System for device pass-through payment status for CY 2019.

(6) Restrata® Wound Matrix

Acera Surgical, Inc. submitted an application for a new device category for transitional pass-through payment status for Restrata® Wound Matrix. Restrata® Wound Matrix is a sterile, single-use product intended for use in local management of wounds. According to the applicant, Restrata® Wound Matrix is a soft, white, conformable, nonfriable, absorbable matrix that works as a wound care management product by acting as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. Restrata® Wound Matrix is made from synthetic biocompatible materials and was designed with a nanoscale nonwoven fibrous structure with high porosity, similar to native extracellular matrix. Restrata® Wound Matrix allows for cellular infiltration, new tissue formation, neovascularization, and wound healing before completely degrading via hydrolysis. The product permits the ingress of cells and soft tissue formation in the defect space/wound bed. Restrata® Wound Matrix can be used to manage wounds, including: Partial and full-thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (for example, donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (for example, abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Restrata® Wound Matrix is a product that is integral to the service provided, is used for one patient only, comes in contact with human skin, and is surgically inserted into the patient. The description of Restrata® Wound Matrix shows the product meets the device eligibility requirements of § 419.66(b)(4) because Restrata® Wound Matrix is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material. We invited public comment on whether Restrata® Wound Matrix meets the eligibility criteria.

We did not receive any public comments on whether Restrata® Wound Matrix meets the eligibility criteria. However, after the CY 2019 OPPS/ASC proposed rule was released, CMS determined that Restrata® Wound Matrix is an alginate dressing described with the HCPCS code series A6196 through A6198 (Alginate or other fiber gelling dressing, wound cover, sterile). Alginate dressings are not skin substitute products and are considered to be a supply. According to the eligibility criterion, a supply or material is not eligible to receive device pass-through payment. Based on this determination, we were required to reassess our initial view on whether or not Restrata® Wound Matrix meets the eligibility criterion for device pass-through payment status.

After consideration of all of the information we have received, we have determined that Restrata® Wound Matrix is an alginate dressing and is a supply, and the product does not meet the eligibility criterion for device pass-through payment status. Because we have determined that Restrata® Wound Matrix does not meet the basic eligibility criterion for transitional pass-through payment status, we have not evaluated this product to determine whether it meets the other criteria required for transitional pass-through payment for devices; that is, the newness criterion, the substantial clinical improvement criterion, and the cost criterion.

After consideration of the public comments we received, we are not approving device pass-through payment status for Restrata® Wound Matrix for CY 2019.

(7) SpaceOAR® System

Augmenix, Inc. submitted an application for a new device category for transitional pass-through payment status for the SpaceOAR® System. According to the applicant, the SpaceOAR® System is a polyethylene glycol hydrogel spacer that temporarily positions the anterior rectal wall away from the prostate to reduce the radiation delivered to the anterior rectum during prostate cancer radiotherapy treatment. The applicant stated that the SpaceOAR® System reduces some of the side effects associated with radiotherapy, which are collectively known as ''rectal toxicity'' (diarrhea, rectal bleeding, painful defecation, and erectile dysfunction, among other conditions). The applicant stated that the SpaceOAR® is implanted several weeks before radiotherapy; the hydrogel maintains space between the prostate and rectum for the entire course of radiotherapy and is completely absorbed by the patient's body within 6 months.

With respect to the newness criterion at § 419.66(b)(1), FDA granted a De Novo request classifying the SpaceOAR® System as a class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on April 1, 2015. We received the application for a new device category for transitional pass-through payment status for the SpaceOAR® System on June 1, 2017, which is within 3 years of the date of the initial FDA approval or clearance. We invited public comments on whether the SpaceOAR® System meets the newness criterion.

Comment: The manufacturer of SpaceOAR® System believed this device meets the eligibility criteria for device pass-through payment, but did not specifically comment on the newness criterion.

Response: We appreciate the manufacturer's input.

After consideration of the public comments we received, we believe that the SpaceOAR® System meets the newness criterion for device pass-through payment status.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the SpaceOAR® System is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed the SpaceOAR® System meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We have not identified an existing pass-through payment category that describes the SpaceOAR® System. The applicant suggested a category descriptor for the SpaceOAR® System of ''Absorbable perirectal spacer''. We invited public comments on this issue.

Comment: The manufacturer of the SpaceOAR® System believed that this device meets the eligibility criteria for device pass-through payment status, but did not specifically comment on whether a current pass-through payment

category appropriately describes this device.

Response: We appreciate the manufacturer's input.

After consideration of the public comments we received, we believe that there is no existing pass-through payment category that appropriately describes the SpaceOAR® System and that the SpaceOAR® System meets the eligibility criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment. With respect to this criterion, the applicant submitted studies which discussed the techniques for using hydrogel spacers to limit radiation exposure to the rectum in prostate radiotherapy. In support of its assertion that SpaceOAR is a substantial clinical improvement, the applicant submitted several studies that examined the effect that the SpaceOAR® System had on outcomes such as rectal dose, radiation toxicity, and quality of life declines after image guided intensity modulated radiation therapy for prostate cancer. Articles by Mariados et al.[25] and Hamstra et al.[26] discussed the results of a single-blind phase III trial of image guided intensity modulated radiation therapy with 15 months and 3 years of follow-up, respectively. In the studies, a total of 222 men were randomized 2:1 to the spacer or control group and received 79.2 Gy in 1.8-Gy fractions to the prostate with or without the seminal vesicles.

The results of this study [27] showed that after 3 years, compared with the control group, the participants who received the SpaceOAR® System injection had a statistically significant smaller volume of the rectum receiving a threshold radiation exposure, which was the primary effectiveness endpoint. The results also showed that in an extended follow up period, the control group experienced larger declines in bowel and urinary quality of life compared to participants who received the SpaceOAR® System treatment. Lastly, in an extended follow-up period, the probability of grade ≥1 rectal toxicity was decreased in the SpaceOAR® System arm (9 percent control group, 2 percent SpaceOAR® System group, p <.03) and no ≥ grade 2 rectal toxicity was observed in the SpaceOAR® System arm. However, the control arm had low rates of rectal toxicity in general. The results of this 3-year follow-up of these participants showed that the differences identified in the 15-month follow-up study were maintained or increased.[28]

The applicant also included a secondary analysis of the phase III trial data which showed that participants who received lower radiation doses to the penile bulb, associated with the SpaceOAR® System injection, reported similar erectile function compared with the control group based on patient-reported sexual quality of life.[29] A 2017 retrospective cohort study by Pinkawa et al.[30] evaluated quality of life changes up to 5 years after RT for prostate cancer with the SpaceOAR® System and showed that 5 years after radiation therapy, no patients who received the SpaceOAR® System reported moderate/big problems with bowel urgency, losing control of stools, or with bowel habits overall. However, there were no statistically significant differences in mean score changes for urinary, bowel, or sexual bother between the percentage of participants in the SpaceOAR® System and control groups at either 1½ years or 5 years postradiation therapy. CMS had concerns regarding the phase III trial include inclusion of only low to moderate risk prostate cancer in the study population and failing to use a clinical outcome as a primary endpoint, although the purpose of the spacer is to reduce the side effects of undesired radiation to the rectum including bleeding, diarrhea, fistula, pain, and/or stricture. Notwithstanding acknowledgement that rectal complications may be reduced using biodegradable biomaterials placed to increase the distance between the rectum and the prostate, it is not clear that the SpaceOAR® System is superior to existing alternative biodegradable biomaterials currently utilized for spacing in the context of prostate radiotherapy.

Based on the evidence submitted with the application, we have insufficient evidence that the SpaceOAR® System provides a substantial clinical improvement over other similar products. We invited public comments on whether the SpaceOAR® System meets the substantial clinical improvement criterion.

Comment: The manufacturer of the SpaceOAR® System identified several points which supported this device meeting the substantial clinical improvement criterion. In response to the statement in the proposed rule that the control arm of the phase III trial had low rates of rectal toxicity in general, the manufacturer noted that the low rates of rectal toxicity in the control arm of the study were due to: (1) The radiation plans in both the treatment and control groups were evaluated and approved by an independent core laboratory for compliance to protocol guidelines, which led to low toxicity in the control group relative to standard practice; and (2) all study dose plans used CT and MRI image fusion to improve plan accuracy, while typical plans only use CT imaging. The manufacturer noted that patients in the SpaceOAR® System group still had statistically significant reductions in rectal toxicity and improvements in quality of life in comparison to the control group.

The manufacturer disagreed with a statement in the proposed rule where CMS indicated that the SpaceOAR® System patients ''reported similar erectile function compared with the control group based on patient-reported sexual quality of life.'' The commenter noted that the patient reported quality of life analysis of baseline potent men at three years found that men treated with the SpaceOAR® System had improved scores on ''erections sufficient for intercourse'' as well as better scores on seven of the 13 items regarding sexual function.[31]

In response to the statement in the proposed rule that the submitted studies included only low to moderate risk prostate cancer in the study population and failed to use a clinical outcome as a primary endpoint, the manufacturer noted that the phase III trial design specifically selected a low and

[25] Mariados N, et al. (2015). Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.92(5)*:971–977. Epub 2015 Apr 23. PMID: 26054865.

[26] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys.* Apr 1;97(5):976–985. Epub 2016 Dec 23. PMID:28209443.

[27] Ibid.

[28] Ibid.

[29] Hamstra, DA et al. (2018) Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: Secondary analysis of a phase 3 trial. *Practical Radiation Oncology, 8,* e7–e15.

[30] Pinkawa, M. et al. (2017). Quality of Life after Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: Five Year Results. *Int J Radiat Oncol Biol Phys., Vol. 99, No. 2,* pp. 374e377.

[31] Hamstra, DA et al. (2018) Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: Secondary analysis of a phase 3 trial. Practical Radiation Oncology, 8, e7–e15.

intermediate risk prostate cancer population to better allow for a safety determination. The manufacturer also noted that the significant reductions in late rectal toxicity and improvements in quality of life at 3 years demonstrate that the clinical benefits of this device are better than anticipated when the study was originally developed.

In response to the statement in the proposed rule that it was unclear that the SpaceOAR® System was superior to existing alternative spacers used for prostate radiotherapy, the manufacturer noted that the SpaceOAR® System is the only prostate-rectum spacer authorized for marketing by the FDA for use in prostate radiotherapy. The manufacturer indicated that the closest comparable product is the endorectal balloon, and that a study comparing the rectal-spacing capabilities of these two products during prostate cancer stereotactic body radiation therapy found significantly less rectal radiation dose in the patients who received the SpaceOAR System®.[32] The manufacturer noted a study of these two products during proton radiotherapy found that, with the SpaceOAR® System, a larger area around the prostate could be radiated while still significantly reducing the rectum radiation dose.[33] The manufacturer indicated that several studies found that prostate stability was comparable using these two products.[34] [35] [36] The manufacturer also noted that reductions in placement error and patient comfort favors the SpaceOAR® System compared to endorectal balloons.[37] The manufacturer asserted that the combined impacts of these results make the SpaceOAR® System a substantial clinical improvement over endorectal balloons.

Several commenters, representing various oncological and urologic specialty societies, believed that the SpaceOAR® System meets the substantial clinical improvement criterion. These commenters noted that there were no other alternative biodegradable biomaterials with FDA marketing authorization currently utilized for spacing in the context of prostate radiotherapy and that this device provided physicians with an option to help ensure patients are provided with the best clinical outcomes with the fewest adverse effects.

Response: We appreciate the manufacturer's and the commenters' input. We reviewed these comments and the associated literature on this topic and found that the application did not support that the SpaceOAR® System demonstrated a substantial clinical improvement as a prostate-rectum spacer for men receiving prostate radiotherapy treatment. While the studies provided by the applicant do indicate that the device provides a dose reduction at the rectum during IMRT for prostate cancer, we found the clinical results of these studies were equivocal and did not provide definitive evidence of substantial clinical improvement of radiation toxicity and quality of life scores after radiation therapy.

In response to our concern that the control arm of the study had very low rates of rectal toxicity (the manufacturers quoted rates of late rectal toxicity of between 14 and 25 percent for studies without the use of the SpaceOAR® System), the commenter responded that the low rates of rectal toxicity in the control arm of the study were due to (1) the radiation plans in both the treatment group and the control group were evaluated and approved by an independent core laboratory for compliance with protocol guidelines, which led to low toxicity in the control group relative to standard practice, and (2) all study dose plans used CT and MRI image fusion to improve plan accuracy, while typical plans only use CT imaging. The commenter further noted that, despite low rates of rectal toxicity in the control arm of the phase III trial, patients in the SpaceOAR® System group still had statistically significant reductions in rectal toxicity and improvements in quality of life in comparison to the control group. We are still concerned that the low rates of rectal toxicity demonstrated in the control group may not support claims of substantial clinical improvement of the SpaceOAR® System. For example, the rates of late grade one or higher rectal toxicity in the control population in the clinical trials submitted by the applicant were 7 percent [38] and 9.2 percent,[39] respectively. The rates of late grade one or higher rectal toxicity in the SpaceOAR® System groups in the clinical trials submitted by the applicant were 2 percent in both studies.[40] [41] We note that image guided radiation therapy has drastically improved radiation dose effects, and conventional radiotherapy is well tolerated by the vast majority of patients.[42] It remains unclear if further reduction in radiation dose effects with the SpaceOAR® System translates to a substantial clinical improvement that is maintained over time when compared to patients who did not receive the SpaceOAR® System. The applicant's explanation that all study dose plans used CT and MRI image fusion to improve plan accuracy, while typical plans only use CT imaging is not supported in the literature, which states that IMRT is considered the standard of care in RT treatment centers; in both the United States and Europe, it has largely replaced older forms of 3D–CRT.[43] [44] The response that the radiation plans in both the treatment group and the control group were evaluated and approved by an independent core laboratory for compliance to protocol guidelines, which led to low toxicity in the control group relative to standard practice, further calls into question the direct role of the SpaceOAR® System in reducing toxicity versus more precise planning

[32] Jones, RT et al. Oosimetric comparison of rectal-sparingcapabilities of rectal balloon vs inje ctab:e spacer gelin stereotactic body radiation therapy forprostate cancer: lessons learned from prospective trials. *Medical Dosimetry,* Volume 42, Issue 4, winter 2017, Pages 341–347.

[33] Fagundes MA et al, Evolving Rectal Sparing In Flducfal • BasedImage Guided Proton Therapy for Localized Prostate Cancer. *International Journal of Radiation Oncology • Biology • Physics,* Vol. 96, Issue 2, E279, 2016.

[34] Hedrick SG et al. A comparison between hydrogel spacer and endorectal balloon: An analysis of lntrafraction prostate motion during proton therapy. *J. Appl. Clln. Med. Phys.,* Vol. 18, pp. 106–112, 2017.

[35] Su Z et al. Hvdrogel Spacer Or Gas Release Rectal Balloon, a Comparative Study of Prostate lntrafraction Motion in Proton Therapy. *Med Phys.* 201S;45(6):el 4l.

[36] Rendall R. Comparison of hydrogel spacer and rectal immobilization on Intra-fraction motion efficiency using Image guidance prostate proton therapy. PTCOG 55,PS02, May 27, 2016.

[37] EI-Bassiounl et al. Target motion variability and on-line positioning accuracy during external beam radiation therapy of prostate cancer with an endorectal balloon device. Strahlenther Onkol. 2006 Sep;1S2(9):53l·6.

[38] Mariados N, et al. (2015). Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.* 92(5):971–977. Epub 2015 Apr 23. PMID: 26054865.

[39] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys.* Apr 1;97(5):976–985. Epub 2016 Dec 23. PMID:28209443.

[40] Ibid.

[41] Ibid.

[42] Uhl et al. (2014). Absorbable hydrogel spacer use in men undergoing prostate cancer radiotherapy: 12 month toxicity and proctoscopy results of a prospective multicenter phase II trial. *Radiation Oncology,* 9:96.

[43] Sheets NC, Goldin GH, Meyer AM, Wu Y, Chang Y, Stürmer T, Holmes JA, Reeve BB, Godley PA, Carpenter WR, Chen RC. (2012). Intensity-modulated radiation therapy, proton therapy, or conformal radiation therapy and morbidity and disease control in localized prostate cancer. *JAMA.;* 307(15):1611.

[44] Bauman G, Rumble RB, Chen J, Loblaw A, Warde P, Members of the IMRT Indications Expert Panel.(2012). Intensity-modulated radiotherapy in the treatment of prostate cancer. *Clin Oncol* (R Coll Radiol), Sep;24(7):461–73. Epub 2012 Jun 4.

protocols and the importance of adhering to guidance protocols.

As discussed further below, we continue to have concerns regarding the applicant's claims that the statistically significant reduction in late rectal toxicity as well as the improvements in QOL scores lend to substantial clinical improvement, despite the relatively low rates of rectal toxicity in the control group. We note that the data showing reduction in rectal toxicity and improvements in quality are from studies that were not designed with primary clinical outcomes to show superiority, but rather were designed primarily to evaluate the threshold of radiation exposure to the rectum and adverse events related to the procedure. Consequently, the studied clinical outcomes have many differences that did not meet statistical significance or were not sustained over time.

In the pivotal trial,[45] no differences in acute rectal or urinary toxicity from the time of the procedure through the 3-month visit were observed between the SpaceOAR® System group and the control group. In this study,[46] there was a statistically significant difference noted between the SpaceOAR® System group and the control group in late rectal toxicity (3 to 15 months after the procedure). In the SpaceOAR® System group, 2 percent of the patients (n=3) experienced late rectal toxicity, while 7 percent of patients in the control group (n=5) experienced late rectal toxicity. There was one incidence of the more clinically serious (grade 3) late rectal toxicity reported in the control group and no incidence of grade 4 rectal toxicity in either group.

Even at 3 years after the procedure, the control arm had very low rates of rectal toxicity. The 3-year incidence of grade ≥1 rectal toxicity was 9.2 percent (approximately 4 patients) in the control group versus 2.0 percent (approximately 2 patients) in the SpaceOAR® System group. The cumulative rate of grade ≥2 rectal bowel toxicity was 6 percent at 3 years in the control arm, with no cases of grade ≥2 rectal toxicity in the SpaceOAR® System group.[47]

With regard to corresponding improvements in quality of life, the pivotal trial,[48] at 3 months, showed there was no statistically significant difference between the SpaceOAR® System group and the control group in mean changes in bowel and urinary quality of life domains. Although, at 6, 12, and 15 months, a lower percentage of patients in the SpaceOAR® System group reported declines in bowel quality of life compared to those in the control group, at 15 months, 11.6 percent and 21.4 percent of the SpaceOAR® System patients and the control group patients, respectively, experienced 10-point declines in bowel quality of life. However, this difference was not statistically significant. In terms of urinary quality of life at 6 months, a higher percentage of patients in the control group (22.2 percent) had 10-point urinary declines in comparison to the the SpaceOAR® System group (8.8 percent). However, again the durability of these improvements disappeared over time because there was no difference between the SpaceOAR® System group and the control group in urinary quality of life decline at 12 and 15 months follow-ups.[49]

The commenter claimed that when followed up at 3 years, patients in the phase III trial receiving the SpaceOAR® System prior to their prostate cancer radiotherapy demonstrated significant rectal (bowel), urinary, and sexual benefit. However, we found the data to be inconsistent and unreliable to support this claim. Specifically, in the study including 3 years of follow-up data,[50] quality of life was examined using the Expanded Prostate Cancer Index Composite (EPIC) questionnaire, a comprehensive instrument designed to evaluate patient function and bother after prostate cancer treatment. For the average bowel summary score, both the SpaceOAR® System group and the control group had similar acute declines in bowel quality of life between enrollment and 3 months after treatment. Also, at 3 months after treatment, there were no patients in the control group that reported acute bowel pain while 6.8 percent of the SpaceOAR® System patients reported acute bowel pain.

In this study, the proportion of patients with measurable changes in bowel quality of life meeting the minimally important difference (MID) threshold (5 points) or twice that threshold (10 points) was evaluated. According to the authors, these thresholds give an idea of when patient-reported symptoms are likely to be clinically meaningful to prostate cancer patients, with a 10-point decline indicating a more serious clinical effect. From 6 months through 3 years, more men in the control group had a MID in bowel quality of life meeting the threshold of 5 points, but no difference was found for a 10-point decline. At 3 years, the SpaceOAR® System group patients were less likely than the control group patients to have a detectable decline in bowel quality of life for both MID thresholds (5-point: 41 percent (control) versus 14 percent (the SpaceOAR® System; 10-point: 21 percent (control) versus 5 percent (the SpaceOAR® System).[51] However, more than 30 percent of the patients in both the SpaceOAR® System group (n=55) and the control group (n=27) were lost by the 3-year follow-up and the follow-up data were taken from volunteer centers that decided to continue in the study. It is unclear if the differences observed at 3 years are due to the large number of respondents who did not participate at year 3, resulting in a smaller sample size and more unreliable data. For example, regarding urinary quality of life, when averaged over the entire follow-up duration, no significant difference was found in the mean urinary quality of life between the two groups. However, at the 3-year point, a statistically significant difference was found in urinary quality of life favoring the SpaceOAR® System group compared with the control group.

The researchers in this study also assessed the percent of patients with moderate or big problems in quality of life. The researchers found that, at 3 years, only one item showed a statistically significant difference between the treatment groups (moderate to big bother for urinary frequency: The control group of 18 percent versus the SpaceOAR® System group of 5 percent; $P < .05$). At 3 years after treatment, 2.2 percent of the men in the SpaceOAR® System group evaluated their overall bowel function as a big or moderate bother. This compares to 4.4 percent in the control group, which was not a statistically significant difference. None of the components of rectal bother were statistically significantly better in the men who received the SpaceOAR® System. In contrast, regarding the question of bowel pain, none of the control group patients reported a moderate or big bother after 3 years, while 1.1 percent of the SpaceOAR® System group patients reported that

[45] Mariados N, et al. (2015). Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiat Oncol Biol Phys.* 92(5):971–977. Epub 2015 Apr 23. PMID: 26054865.

[46] Ibid.

[47] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys.* Apr 1;97(5):976–985. Epub 2016 Dec 23. PMID:28209443.

[48] Ibid.

[49] Ibid.

[50] Hamstra DA, et al. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *Int J Radiat Oncol Biol Phys.* Apr 1;97(5):976–985. Epub 2016 Dec 23. PMID:28209443.

[51] Ibid.

bowel pain was a moderate or big bother.[52] The study by Pinkawa et al.[53] looking at 1½ and 5 year results comparing quality of life of patients pretreated with hydrogel and controls further demonstrates inconsistency in looking at substantial improvements with the SpaceOAR® System. In this study percentages of big problems with bowel urgency, control of stools and bowel habitus overall favored SpaceOAR at 1½ years. However, only differences in percentage of problems of bowel urgency remained after the 5-year follow-up. Also, no statistically significant difference was shown between the SpaceOAR® System group and the control group in comparing mean bowl bother scores at 1½ years and 5 years after radiation therapy.

The manufacturer stated that CMS incorrectly stated in the proposed rule that the SpaceOAR® System patients reported similar erectile function compared with the control group based on patient-reported sexual quality of life. The manufacturer is correct; in a study by Hamstra et al.,[54] the patient-reported quality of life analysis of baseline potent men found that men in this group treated with the SpaceOAR® System had improved ''erections sufficient for intercourse'' as well as statistically significant higher scores on 7 of 13 items in the sexual domain in comparison to the control group at 3 years. However, at baseline, sexual functioning in the study was low; only 41 percent of patients had no sexual dysfunction at baseline (EPIC sexual quality of life scores >60, n=88). When comparing men with poor baseline sexual quality of life (EPIC score ≤60, n=125), there was no difference between the SpaceOAR® System group and the control group in function, bother, or sexual summary score at the 3-year follow up.[55] We also note that the Pinkawa [56] study shows that more men with the SpaceOAR® System reported erections firm enough for intercourse to be statistically significant. However, again the same study reported the changes in sexual quality of life bother score were not statistically different between the two groups at 5 years. Again, along with the instability of the 3-year data stated above, the fact that the data are inconsistent and not supported by the long-term quality of life data, we are unable to substantiate substantial clinical improvement.

We appreciate the comments received from the urological and the oncological community as well members of the public in support of this technology. The SpaceOAR® System device effectively displaces the anterior wall reducing the dose of radiation the rectum receives during radiation treatment for prostate cancer. However, after consideration of the public comments and the application materials we received, at this time we do not believe that the SpaceOAR® System meets the substantial clinical improvement criterion to receive device pass-through payment. The submitted studies were not designed to show primary clinical outcomes, and consequently the data on toxicity and quality of life improvement are inconsistent and fail to show enduring improvements. It is difficult to attribute the reductions in late rectal toxicity solely to the device, given improvements in radiation therapy and planning as well as the large number of nonresponders at 3 years postradiation and the 3-year follow-up data were being taken from volunteer centers that decided to continue in the study. We note that many favorable clinical outcomes were not statistically significant but trended in favor of the SpaceOAR® System group. We agree with many authors that seem to suggest that the greatest utility of the SpaceOAR® System will be its use in populations at greatest risk for radiation toxicity such as hypofractionated treatment or other dose intensifications.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the SpaceOAR® System would be reported with CPT code 0438T (which was deleted and replaced with CPT code 55874, effective January 1, 2018). CPT code 0438T was assigned to APC 5374 (Level 4 Urology and Related Services). To meet the cost criterion for device pass-through payment, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5374, which had a CY 2017 payment rate of $2,542.56 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0438T had a device offset amount of $587.07 at the time the application was received. According to the applicant, the cost of the SpaceOAR® System was $2,850.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,850 for the SpaceOAR® System exceeds 112 percent of the applicable APC payment amount for the service related to the category of devices of $2,542.56 ($2850/$2,542.56 × 100 = 112 percent). Therefore, we believe the SpaceOAR® system meets the first cost significance test.

The second cost significance test, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,850 for the SpaceOAR® System exceeds the cost of the device-related portion of the APC payment amount for the related service of $587.07 by 485 percent ($2,850/$587.07) × 100 = 485 percent). Therefore, we believe that the SpaceOAR® System meets the second cost significance test.

The third cost significance test, at § 419.66(d)(3), requires that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,850 for the SpaceOAR® System and the portion of the APC payment amount for the device of $587.07 exceeds the APC payment amount for the related service of $2,542.56 by 89 percent (($2,850 − $587.07)/$2,542.56 × 100 = 89 percent). Therefore, we believe that the SpaceOAR® System meets the third cost significance test.

We invited public comments on whether the SpaceOAR® System meets the device pass-through payment

[52] Ibid.

[53] Pinkawa, M. et al. (2017). Quality of Life after Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: Five Year Results. *Int J Radiat Oncol Biol Phys.,* Vol. 99, No. 2, pp. 374e377.

[54] Hamstra, DA et al. (2018) Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: secondary analysis of a phase 3 trial. *Practical Radiation Oncology,* Vol. 8, e7–e15.

[55] Ibid.

[56] Pinkawa, M. et al. (2017). Quality of Life after Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: Five Year Results. *Int J Radiat Oncol Biol Phys.,* Vol. 99, No. 2, pp. 374e377.

criteria discussed in this section, including the cost criteria.

Comment: The manufacturer of the SpaceOAR® System believed this device meets the eligibility criteria for device pass-through payment status, but did not specifically comment on whether this device meets the cost criterion.

Response: We appreciate the manufacturer's input.

After consideration of the public comments we received, we believe that SpaceOAR® System meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, we believe that SpaceOAR® System does not qualify for device pass-through payment status because it does not meet the substantial clinical improvement criterion, although it may have clinical benefit for certain patients. As such, we are not approving the application for device pass-through payment status for the SpaceOAR® System for CY 2019.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of this final rule with comment period. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APCs were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of APC assignment.

Under our existing policy, procedures that meet the criteria listed below in section IV.B.1.b. of this final rule with comment period are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4. of this final rule with comment period, respectively.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed above—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the above criteria are assigned device-intensive status, regardless of their APC placement.

2. Changes to the Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of CMS' effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC proposed rule (83 FR 37108), for CY 2019, we proposed to modify our criteria for device-intensive procedures. We have heard from stakeholders that the current criteria exclude some procedures that stakeholders believe should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and proposed two modifications to the criteria for CY 2019. First, we proposed to allow procedures that involve surgically inserted or implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless

of whether the device remains in the patient's body after the conclusion of the procedure. We proposed this policy because we no longer believed that whether a device remains in the patient's body should affect its designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we proposed to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated in the proposed rule that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated in the proposed rule that this proposed change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we proposed that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we proposed to specify, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

(a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

As part of this proposal, we solicited public comment on these proposed revised criteria, including whether there are any devices that are not capital equipment that commenters believe should be deemed part of device-intensive procedures that would not meet the proposed definition of single-use devices. In addition, we solicited public comments on the full list of proposed CY 2019 OPPS device-intensive procedures provided in Addendum P to the proposed rule, which is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*. Specifically, we invited public comment on whether any procedures proposed to receive device-intensive status for CY 2019 should not receive device-intensive status according to the proposed criteria, or if we did not assign device-intensive status for CY 2019 to any procedures commenters believed should receive device-intensive status based on the proposed criteria.

Comment: The majority of commenters supported CMS' proposal to modify the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. The commenters believed that this proposed policy change will better support accurate payment for procedures where an implantable device is a significant proportion of the total cost of the procedure. Some commenters indicated that this proposed change would help to spur innovation in the device industry.

Response: We appreciate the commenters' support.

Comment: The majority of commenters supported the proposal to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent. The commenters believed that this proposed policy change will encourage migration of services from the hospital outpatient department into the ASC setting, resulting in cost savings to the Medicare program and Medicare beneficiaries. Some of these commenters encouraged CMS to further modify its proposal and instead lower the device offset percentage threshold for procedures to qualify as device-intensive to 25 percent instead of 30 percent, to allow even more procedures to be designated as device-intensive.

Response: We appreciate commenters' support. At this time, we continue to believe that applying a device offset percentage threshold of greater than 30 percent for procedures to qualify as device-intensive is most appropriate for the reasons described in our original proposal. Because the ASC payment system is budget neutral, when the device-intensive threshold is set lower, it results in transfer of payment from services with high device offsets or that do not qualify as device-intensive to the services being newly designated as device-intensive. As a result, it is important that the device-intensive threshold not be set too low or it will result in the transfer of payments from procedures with high device offsets to procedures with low device offsets, which is the opposite of the intended purpose of this policy. We will take the commenters' suggestion of applying a device offset percentage threshold of greater than 25 percent for procedures to qualify as device-intensive into consideration for future rulemaking.

In addition, for new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a medical device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent is not calculated from claims data; instead, it is applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert medical devices is to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37108 through 37109), in accordance with our proposal stated above to lower the

device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we proposed to modify this policy and apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a medical device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the proposal to lower the default device offset from 41 percent to 31 percent, we proposed to continue our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation of a medical device, device-intensive status will be applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the proposed rule, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we proposed to use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code. Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this proposal, claims data from clinically related and similar codes would be included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we proposed to apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated in the proposed rule that we believe that claims data for HCPCS codes describing procedures that have very minor differences from the procedures described by new HCPCS codes would provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and would be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. For instance, for CY 2019, we proposed to use the claims data from existing CPT code 36568 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump; younger than 5 years of age), for which the description as of January 1, 2019 is changing to ''(Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, without imaging guidance; younger than 5 years of age)'', to determine the appropriate device offset percentage for new CPT code 36X72 (Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age). We believe that although CPT code 36568 is not identified as a predecessor code by CPT, the procedure described by new CPT code 36X72 was previously described by CPT code 36568 and, therefore, CPT code 36X72 is clinically related and similar to CPT code 36568, and the device offset percentage for CPT code 36568 can be accurately applied to both codes. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage would be used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage would be used to determine whether the new HCPCS code qualifies for device-intensive status.

In the CY 2019 OPPS/ASC proposed rule, we indicated that additional information for our consideration of an offset percentage higher than the proposed default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a medical device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of proposed CY 2019 OPPS device-intensive procedures was included in Addendum P to the proposed rule (which is available via the internet on the CMS website).

Comment: Commenters supported the proposal to apply a default device offset of 31 percent to procedures requiring devices that do not yet have claims data, as well as the proposal to use claims data from clinically similar and related codes to establish device offsets for procedures with new codes that do not have direct predecessor codes according to CPT.

Response: We appreciate the commenters' support.

Comment: A few commenters suggested that CMS only adjust the non-device portion of the payment by the wage index, consistent with the Agency's policy for separately payable drugs and biologicals.

Response: While we did not make such a proposal in this year's proposed rule, we will take this comment into consideration for future rulemaking. We note that such a policy would increase payments to providers with a wage index value of less than 1 and be offset by a budget neutral decrease in payments to other providers.

Comment: A group of commenters urged CMS to calculate the device offset percentage for potential device-intensive procedures using the standard (noncomprehensive APC) ASC ratesetting methodology and to assign device-intensive status in the ASC system based on that device offset percentage, as they believed it is more consistent with the overall ASC payment system. One commenter requested some clarification in the final

rule about the current methodology for calculating the device offset percentage for device-intensive procedures and specifically asked that CMS:

- Confirm that the ASC device-intensive status as assigned by CMS is based on the offset calculated according to the ASC ratesetting methodology;
- Disclose what offset data (meaning the calculation methodology used) appear in the second spreadsheet of Addendum P titled ''2019 NPRM HCPCS Offsets'';
- Display the device offsets in Addendum P, in future rulemaking, based on the ASC methodology and not the OPPS methodology if the offset data displayed in the second spreadsheet of Addendum P is based on the OPPS methodology and device intensive status is based on the ASC methodology; and
- Modify the second worksheet of Addendum P titled ''2019 NPRM HCPCS Offsets'' to only include the codes for procedures that employ implantable and insertable devices and exclude all of the codes that do not employ implantable or insertable devices.

Response: As stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37158), according to our established ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system.

In response to the commenter's questions and suggestions relating to Addendum P, we note that the device offset percentages reflected in both worksheets of Addendum P are based upon the OPPS methodology (including the C–APC methodology). We believe this is appropriate as Addendum P is created to display the device offsets, device offset percentages, and device-intensive codes under the OPPS. Specific to the commenter's suggestion that we modify the second worksheet of Addendum P titled ''2019 NPRM HCPCS Offsets'' to only include the codes for procedures that employ implantable and insertable devices and exclude all of the codes that do not employ implantable or insertable devices, we note that the second worksheet of Addendum P is intended to display the device offsets and device offset percentages for all codes for which we have such data under the OPPS. In addition, the list of services that qualify as device-intensive under the ASC payment system and the services' device offset percentages for the ASC payment system are included on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html* as ''CY 2019 Final ASC Device-Intensive Procedures and Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies.''

Comment: Commenters supported the proposed device-intensive status for the following CPT codes:

- CPT code 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method);
- CPT code 28730 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse);
- CPT code 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint);
- CPT code 36903 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment);
- CPT code 36904 (Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s)); and
- CPT code 36906 (Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit).

Other commenters requested that CMS assign device-intensive status to:

- HCPCS code C9747 (Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance);
- CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed);
- CPT code 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (*e.g.,* fluoroscopic, ct), single or multiple levels, unilateral or bilateral; lumbar);
- CPT code 55874 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed);
- CPT code 0409T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only);
- CPT code 0410T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only);
- CPT code 0411T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only); and
- CPT code 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only).

Response: We appreciate the commenters' support. With respect to the commenters' request that we assign the device-intensive designation to

HCPCS code C9747 and CPT codes 43210, 0275T, and 55874, we note that the device offset percentage for all four of these procedures (as identified by the above mentioned HCPCS codes or predecessor codes) is not above the 30-percent threshold, and therefore these procedures are not eligible to be assigned device-intensive status. CPT codes 0409T, 0410T, 0411T, and 0414T were inadvertently omitted from the listing of proposed device-intensive procedures in the CY 2019 OPPS/ASC proposed rule. However, we have included them as device-intensive procedures in this final rule with comment period. CPT code 36904 was proposed as a device-intensive procedure. However, using the most currently available data for this CY 2019 OPPS/ASC final rule with comment period, we have determined that its device offset percentage is not above the 30-percent threshold, and therefore this procedure is not eligible to be assigned device-intensive status.

Comment: One commenter stated that CPT code 86891 (Autologous blood or component, collection processing and storage; intra- or postoperative salvage) was incorrectly proposed to have device-intensive status for CY 2019.

Response: We agree with the commenter. CPT code 86891 was inadvertently included in the listing of device-intensive procedures in Addendum P to the CY 2019 OPPS/ASC proposed rule.

After consideration of the public comments we received, we are finalizing our proposals to allow procedures that involve surgically inserted or implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure and to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The full listing of the final CY 2019 device-intensive procedures is included in Addendum P to this final rule with comment period (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure.

We did not propose any changes to this policy for CY 2019.

Comment: Some commenters expressed concern about a potential claims processing issue that would arise from a number of codes (listed below in Table 36) that were proposed to have device-intensive status, which, in their clinical opinion, do not always require the involvement of implantable or insertable single-use devices and, therefore, could be subject to the claims edit requiring device-intensive procedures to be billed with a device., when the procedure may not require the involvement of a device.

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TABLE 36.—LIST OF CODES PROPOSED TO HAVE DEVICE-INTENSIVE STATUS IDENTIFIED BY COMMENTERS THAT DO NOT ALWAYS REQUIRE THE INVOLVEMENT OF A DEVICE AND THAT INCORRECTLY MAY BE SUBJECT TO CLAIMS DEVICE EDIT

HCPCS Code	Long Descriptor
23585	Open treatment of scapular fracture (body, glenoid or acromion) includes internal fixation, when performed
24685	Open treatment of ulnar fracture, proximal end (eg, olecranon or coronoid process[es]), includes internal fixation, when performed
27784	Open treatment of proximal fibula or shaft fracture, includes internal fixation, when performed
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed
28555	Open treatment of tarsal bone dislocation, includes internal fixation, when performed
24575	Open treatment of humeral epicondylar fracture, medial or lateral, includes internal fixation, when performed
27814	Open treatment of bimalleolar ankle fracture (eg, lateral and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed
28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation
25525	Open treatment of radial shaft fracture, includes internal fixation, when performed, and closed treatment of distal radioulnar joint dislocation (Galeazzi fracture/dislocation), includes percutaneous skeletal fixation, when performed
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip
25515	Open treatment of radial shaft fracture, includes internal fixation, when performed
28465	Open treatment of tarsal bone fracture (except talus and calcaneus), includes internal fixation, when performed, each
24579	Open treatment of humeral condylar fracture, medial or lateral, includes internal fixation, when performed
28615	Open treatment of tarsometatarsal joint dislocation, includes internal fixation, when performed
28445	Open treatment of talus fracture, includes internal fixation, when performed
23515	Open treatment of clavicular fracture, includes internal fixation, when performed
23680	Open treatment of shoulder dislocation, with surgical or anatomical neck fracture, includes internal fixation, when performed

HCPCS Code	Long Descriptor
27832	Open treatment of proximal tibiofibular joint dislocation, includes internal fixation, when performed, or with excision of proximal fibula
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy

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Response: We have noted the commenters' concern. We have performed a clinical examination of the potential device-intensive procedures and believe the codes listed in Addendum P to this CY 2019 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website) as OPPS device-intensive meet the newly finalized criteria of being a device-intensive procedure. To address any potential claims processing issues pertaining to the device edit policy, we will use subregulatory authority to ensure that the device edit does not improperly prevent correctly coded claims from being paid.

Comment: One commenter requested that CMS either revise the descriptor for HCPCS code C1889 (Implantable/insertable device for device-intensive procedure, not otherwise classified) to remove the specific applicability to device-intensive procedures or establish a new ''Not Otherwise Classified'' (NOC) HCPCS code for devices that do not have a specific device HCPCS code or are used in a procedure not designated as device-intensive.

Response: We agree with the commenter and have revised the NOC HCPCS code to remove the specific applicability to device-intensive procedures. HCPCS code C1889 now reads ''(Implantable/insertable device, not otherwise classified)''.

Comment: One commenter requested that CMS restore the device-to-procedure and procedure-to-device edits.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the more costly devices, we believe the C–APCs will reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We note that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also note that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Medical Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would

apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized our policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37110), for CY 2019 and subsequent years, we proposed to apply our no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under our proposed modified criteria discussed in section IV.B.2. of the proposed rule and this final rule with comment period.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to apply our no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under our finalized modified criteria discussed in section IV.B.2. of this final rule with comment period, for CY 2019 and subsequent years.

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We note that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs), and we believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be calculated using the median cost instead of the geometric mean cost, for the reasons described above for the policy applied to the procedure described by CPT code 0308T in CY 2016. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was approximately $21,302, and the median cost was approximately $19,521. The final CY 2018 payment rate (calculated using the median cost) was approximately $17,560.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37111), for CY 2019, we proposed to continue with our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. We stated in the proposed rule that, due to the proposed change in APC assignment for CPT code 0308T to APC 5493 (Level 3 Intraocular Procedures) from APC 5495 (Level 5 Intraocular Procedures), our payment policy for low-volume device-intensive procedures would not apply to CPT code 0308T for CY 2019 because there are now more than 100 total claims for the APC to which CPT code 0308T would be assigned. For more information on the proposed and final APC assignment change for CPT code 0308T, we refer readers to section III.D.13. of this final rule with comment period.

Based on the CY 2017 claims data available for ratesetting, in the CY 2019 OPPS/ASC proposed rule, we proposed to assign CPT code 0308T to APC 5493, noting that we would continue to monitor the data. In the CY 2019 OPPS final rule claims data, we found that the estimated cost of the single claim with CPT code 0308T as the primary service is $12,939.75. To recognize the estimated cost based on the final rule claims data, we have assigned CPT code 0308T to APC 5494 (Level 4 Intraocular Procedures) for CY 2019 instead of APC 5493. Due to the assignment of CPT code 0308T to APC 5494 for CY 2019, our payment policy for low-volume device-intensive procedures will apply to CPT code 0308T for CY 2019 because there are less than 100 total claims for the APC to which CPT code 0308T is assigned. For more information on the proposed and final APC assignment change for CPT code 0308T, including a summary of public comments and our responses, we refer readers to section III.D.13. of this final rule with comment period.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this final rule with comment period, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined in the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs

and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. CY 2019 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals is described on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Three-Year Transitional Pass-Through Payment Period for All Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2018

In the CY 2019 OPPS/ASC proposed rule (83 FR 37112), we proposed that the pass-through payment status of 23 drugs and biologicals would expire on December 31, 2018, as listed in Table 19 of the proposed rule (83 FR 37112). All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018. These drugs and biologicals were approved for pass-through payment status on or before January 1, 2017. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is $125 for CY 2019), as discussed further in section V.B.2. of this final rule with comment period. In the CY 2019 OPPS/ASC proposed rule (83 FR 37112), we proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which was proposed at ASP+6 percent for CY 2019, and is finalized at ASP+6 percent for CY 2019, as discussed further in section V.B.3. of this final rule with comment period).

Comment: A number of commenters requested that pass-through payment status for HCPCS code A9515 (Choline

c-11, diagnostic, per study dose up to 20 millicuries) be extended until March 2019 to give 3 full years of pass-through payment status for the drug. The drug described by HCPCS code A9515 received pass-through status in April 2016, and in the CY 2019 OPPS/ASC proposed rule, the pass-through payment period for the drug was scheduled to end on December 31, 2018, consistent with the policy in effect in CY 2016 that drugs and biologicals receive at least 2 years but no more than 3 years of pass-through payment status where pass-through payment status for drugs and biologicals was expired on an annual basis through notice-and-comment rulemaking. One commenter requested an extension of pass-through payment status to allow for the collection of more cost data for HCPCS code A9515. Another commenter believed pass-through payment status for HCPCS code A9515 should be extended because of concern that the cost of HCPCS code A9515 exceeds the payment rate for the nuclear medicine services with which HCPCS code A9515 will be packaged. The commenter cited data showing the pass-through payment rate for HCPCS code A9515 was $5,700, while the highest APC payment rate for a nuclear medicine service was $1,377.22 with a drug offset of $248.31. Two commenters also requested that HCPCS codes Q9982 (Flutemetamol f18, diagnostic, per study dose, up to 5 millicuries) and Q9983 (Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries) not be taken off of pass-through payment status due to similar concerns.

Response: As noted in the proposed rule, all three radiopharmaceuticals are covered under the pass-through payment expiration policy in effect in CY 2016 which stated that drugs and biologicals receive at least 2 years and no more than 3 years of pass-through payment status, with the pass-through payment period expiring at the end of a calendar year. Beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, a new policy is in effect to allow for a quarterly expiration of pass-through payment status for drugs and biologicals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals (82 FR 59337). HCPCS codes A9515, Q9982, and Q9983 are covered by the policy in effect for CY 2016, and pass-through payment status for these HCPCS codes will end on December 31, 2018. We note that when a radiopharmaceutical or other drug or biological is newly packaged into a related medical procedure, the amount of the payment rate for the related medical procedure does not stay the same. Instead, the payment rate for the medical procedure will be adjusted to reflect the additional cost of the newly packaged radiopharmaceutical in the overall cost of the medical procedure.

Comment: Some commenters recommended that CMS allow products covered by Medicare in the context of a coverage with evidence development (CED) clinical trial to retain their pass-through payment status for the duration of the CED trial. Two of the commenters focused on the packaging of diagnostic radiopharmaceuticals that do not have pass-through payment status. One of the commenters requested that pass-through payment status for Neuraceq™ (florbetaben F18, HCPCS code Q9982) and Vizamyl™ (flutemetamol F18, HCPCS code Q9983), which is scheduled to end on December 31, 2018, be extended because of a current CED trial for amyloid positron emission tomography (PET) that will be active through at least CY 2019. (Information on this CED trial can be found on the CMS website at *https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.html*). This commenter also suggested that if pass-through payment status is not extended, these drugs could be paid separately under their own assigned APCs to avoid having the cost of these drugs packaged into the primary procedures for which they are used. Another commenter was more broadly concerned about not receiving payment for a drug or biological when a CED trial is ongoing and a drug or biological used in the trial loses pass-through payment status and becomes packaged. The commenters were concerned that ending pass-through payment for drugs that will no longer be paid separately could negatively impact CED trials as hospitals would be less likely to participate because of the risk of receiving lower payment for the services covered by the CED trial.

Response: We disagree with the commenters' concern that expiration of pass-through payment status for Neuraceq™ (HCPCS code Q9982) and Vizamyl™ (HCPCS code Q9983), and subsequent packaging of them as ''policy-packaged'' drugs, will affect trial results. We note that hospitals are not precluded from billing for Neuraceq™ and Vizamyl™ in the context of a CED trial once their pass-through payment status expires. We also note that the payment for both Neuraceq™ and Vizamyl™ will be reflected in the payment rate for the associated procedure. With respect to the request that we create a new APC for Neuraceq™ and Vizamyl™, we do not believe it is appropriate, prudent, or practicable to create unique APCs for specific drugs or biologicals or other individual items that are furnished with a particular procedure or procedures. Finally, with respect to the commenters' request that we allow drug or biological pass-through payment status for products covered by a CED trial for the duration of the CED trial, we reiterate that the statute limits the period of pass-through payment eligibility to no more than 3 years after the product's first payment as a hospital outpatient service under Medicare Part B. As such, we are unable to extend pass-through payment status beyond 3 years.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to expire the pass-through payment status of the 23 drugs and biologicals listed in Table 37 below on December 31, 2018.

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TABLE 37.—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS EXPIRES DECEMBER 31, 2018

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 Status Indicator	Final CY 2019 APC	Pass-Through Payment Effective Date
A9515	Choline C 11, diagnostic, per study dose	N	N/A	04/01/2016
C9460	Injection, cangrelor, 1 mg	K	9460	01/01/2016
C9482	Injection, sotalol hydrochloride, 1 mg	K	9482	10/01/2016
J1942	Injection, aripiprazole lauroxil, 1 mg	K	9470	04/01/2016
J2182	Injection, mepolizumab, 1 mg	K	9473	04/01/2016
J2786	Injection, reslizumab, 1 mg	K	9481	10/01/2016
J2840	Injection, sebelipase alfa, 1 mg	K	9478	07/01/2016
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	K	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	K	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	K	1846	04/01/2016
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	K	9471	04/01/2016
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	K	9479	07/01/2016
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	K	1845	04/01/2016
J9022	Injection, atezolizumab, 10 mg	K	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	K	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	K	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	K	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	K	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	K	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	K	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	K	1822	07/01/2015
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	N	N/A	01/01/2016
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	N	N/A	01/01/2016

The final packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

4. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Payment Status in CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37112), we proposed to continue pass-through payment status in CY 2019 for 45 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between January 1, 2017, and July 1, 2018, were listed in Table 20 of the proposed rule (83 FR 37113 through 37114). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through

payment status through December 31, 2018 were assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website). In addition, as indicated in the proposed rule, there are four drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status is required to be extended for an additional 2 years under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141). Because of this requirement, these drugs and biologicals were also included in Table 20 of the proposed rule, which brought the total number of drugs and biologicals with proposed pass-through payment status in CY 2019 to 49. The requirements of section 1301 of Public Law 115–141 are described in further detail in section V.A.5. of this final rule with comment period, and we address public comments that we received related to this topic in that section.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2019, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2019. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2019 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2019 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of the proposed rule. We made this proposal because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2019 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2019, consistent with our CY 2018 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2019, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail and comments on the WAC+3 percent payment policy can be found in section V.B.2.b. of this final rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We did not receive any public comments regarding our proposals. Therefore, we are implementing these proposals for CY 2019 without modification. We note that public comments pertaining to our proposal to pay WAC+3 percent for drugs and biologicals without ASP information as well as public comments on section 1301 pass-through payment status extensions are addressed elsewhere in this final rule with comment period.

The drugs and biologicals that continue to have pass-through payment status for CY 2019 or have been granted pass-through payment status as of January 2019 are shown in Table 38 below.

TABLE 38.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018
A9587	A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9014	J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018
C9015	J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018
C9016	J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018
C9024	J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
C9028	J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9029	J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018
C9030	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9031	A9513	Lutetium Lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018
C9032	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018
C9033	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018
C9034	C9034	Injection, dexamethasone 9%, intraocular, 1 mcg	G	9172	10/01/2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018
C9463	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018
C9464	J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
C9465	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018
C9466	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018
C9467	J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018
C9468	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018
C9488	C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017
C9492	J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017
C9493	J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017
J0565	J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J1428	J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
J1627	J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2326	J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
J2350	J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J3358	J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
J7179	J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J7328	J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	01/01/2016
J7345	J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018
J9023	J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
N/A	Q2042*	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018
Q4172	Q4195	Puraply, per square centimeter	G	9175	10/01/2018
Q4172	Q4196	Puraply am, per square centimeter	G	9176	10/01/2018
Q5103	Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018
Q5105	Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073	07/01/2018
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239	07/01/2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
Q9993	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018
N/A	C9035	Injection, aripiprazole lauroxil, 1 mg	G	9179	01/01/2019
N/A	C9036	Injection, patisiran, 0.1 mg	G	9180	01/01/2019
N/A	C9037	Injection, risperidone (Perseris), 0.5 mg	G	9181	01/01/2019
N/A	C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019
N/A	C9039	Injection, plazomicin, 5 mg	G	9183	01/01/2019
N/A	C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184	01/01/2019
N/A	C9408	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9185	01/01/2019

* HCPCS code Q2040 (Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion) will be deleted on December 31, 2018 and will be replaced by Q2042 (Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose) on January 1, 2019.

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5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141)

As mentioned earlier, section 1301(a)(1) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141) amended section 1833(t)(6) of the Act and added a new section 1833(t)(6)(G), which provides that for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020. There are four products whose period of drug and biological pass-through payment status ended on December 31, 2017. These products were listed in Table 21 of the CY 2019 OPPS/ASC proposed rule (83 FR 37115). For CY 2019, we proposed to continue pass-through payment status for the drugs and biologicals listed in Table 21 of the proposed rule (we note that these drugs and biologicals were also listed in Table 20 of the proposed rule). The APCs and HCPCS codes for these drugs and biologicals approved for pass-through payment status were assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

In addition, new section 1833(t)(6)(H) of the Act specifies that the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of: (i) The payment amount that would otherwise apply under section 1833(t)(6)(D)(i) of the Act for such drug or biological during such period; or (ii) the payment amount that applied under section 1833(t)(6)(D)(i) of the Act for such drug or biological on December 31, 2017. We stated in the proposed rule that we intended to address pass-through payment for these drugs and biologicals for the last quarter of CY 2018 through program instruction. The program instruction covering pass-through payment for these drugs and biologicals for the last quarter of CY 2018 is Transmittal 4123 titled ''October 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)'', and can be found on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/*

2018Downloads/R4123CP.pdf. For January 1, 2019 through March 31, 2019, we proposed that pass-through payment for these four drugs and biologicals would be the greater of: (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. We also proposed for the period of April 1, 2019 through December 31, 2019 that the pass-through payment amount for these drugs and biologicals would be the amount that applies under section 1833(t)(6)(D)(i) of the Act.

We proposed to continue to update pass-through payment rates for these four drugs and biologicals on a quarterly basis on the CMS website during CY 2019 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

The four drugs and biologicals that we proposed would have pass-through payment status for CY 2019 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, were shown in Table 21 of the CY 2019 OPPS/ASC proposed rule (83 FR 37115). Included as one of the four drugs and biologicals with pass-through payment status for CY 2019 is HCPCS code Q4172 (Puraply, and Puraply AM per square centimeter). PuraPly is a skin substitute product that was approved for pass-through payment status on January 1, 2015 through the drug and biological pass-through payment process. Beginning on April 1, 2015, skin substitute products are evaluated for pass-through payment status through the device pass-through payment process. However, we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66887) that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. Because PuraPly was approved for pass-through payment status through the drug and biological pass-through payment pathway, we proposed to consider PuraPly to be a drug or biological as described by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, and to be eligible for extended pass-through payment under our proposal for CY 2019.

Comment: Several commenters were opposed to PuraPly and PuraPly AM receiving pass-through payment status for CY 2019. These commenters stated that because PuraPly and PuraPly AM received a 510(k) clearance from the FDA, PuraPly and PuraPly AM should be considered devices rather than drugs or biologicals or that there is at least some ambiguity about whether PuraPly and PuraPly AM are devices. The commenters encouraged CMS to use its discretion and consider PuraPly and PuraPly AM to be devices along the same lines of reasoning as CMS has considered biologicals used as skin substitutes to be considered devices for the purposes of receiving pass-through payment since April 2015. In addition, the commenters noted that PuraPly and PuraPly AM should not have pass-through payment status extended because they are no longer new products. Further, the commenters noted that these products would receive a significant market advantage by being the only graft skin substitute product to receive separate payment. Other commenters noted that extending the pass-through payment status of PuraPly and PuraPly AM would work against the goals CMS has stated in other parts of the proposed rule regarding skin substitute payment. Finally, these commenters maintained that extending pass-through payment status would encourage the use of more high-cost skin substitute products and lead to increased pricing instability by increasing the cost thresholds for the high-cost skin substitute group. Another commenter opposed extending pass-through payment status for PuraPly and PuraPly AM based on the belief that the manufacturer of these products may be unfairly increasing the prices for these products when they return to pass-through payment status.

Response: In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66887), we stated that skin substitutes that are approved for pass-through payment status as biologicals effective on or before January 1, 2015 would continue to be paid as pass-through biologicals for the duration of their pass-through payment period. PuraPly and PuraPly AM were originally approved for pass-through payment status on January 1, 2015 under the drug and biological pass-through payment pathway as biologicals. We interpret section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, as extending the original pass-through payment period that was established for PuraPly and PuraPly AM on January 1, 2015, and therefore, PuraPly and PuraPly AM will continue to be paid as pass-through drugs and biologicals. While we acknowledge the comments pointing out that we currently treat skin substitute products as devices for purposes of pass-through payment status, this does not change the fact that PuraPly and PuraPly AM were originally approved for pass-through payments as biologicals. We believe that PuraPly and PuraPly AM's original approval for pass-through status as biologicals means that they should continue to receive pass-through payments under section 1833(t)(6)(G) of the Act.

We also recognize that the commenters raised important concerns about the impact that extending pass-through payment status for PuraPly and PuraPly AM could have on the payment of wound care services using graft skin substitute products. However, we nonetheless believe that section 1833(t)(6)(G) of the Act requires us to extend the pass-through payment period for PuraPly and PuraPly AM.

Comment: One commenter, the manufacturer of PuraPly and PuraPly AM, urged CMS to implement the proposal to give PuraPly and PuraPly AM pass-through payment status based on the requirements of section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. The commenter stated that PuraPly and PuraPly AM are biologicals and cited language in OPPS regulations supporting that designation. The commenter also made the point that the pass-through payment status granted to PuraPly and PuraPly AM starting on October 1, 2018 was described in the statute as an extension of the original pass-through payment status and not a new pass-through payment period. The commenter stated that this means the requirements in effect when pass-through payment status for PuraPly and PuraPly AM was established on January 1, 2015 apply to the extended pass-through payment period. The commenter noted that CMS changed how skin substitute products are evaluated for pass-through payment status by evaluating skin substitutes through the medical device pass-through pathway in April of 2015, but emphasized that the change was not retroactive. Therefore, the commenter agreed that PuraPly and PuraPly AM should continue to receive pass-through payment status.

Several members of Congress supported extending pass-through payment status for PuraPly and PuraPly

AM and requested that CMS consider the products to be biologicals that are covered by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018.

Response: We appreciate the commenters' support. We are finalizing our proposal to extend pass-through payment status for PuraPly and PuraPly AM based on section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018.

Comment: One commenter, the manufacturer of Omidria (HCPCS code C9447), supported the extended pass-through payment status for Omidria. Likewise, a second commenter, the manufacturer of Lumason® (HCPCS code Q9950), supported the extended pass-through payment status for Lumason®.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposals, with modification, to accommodate a coding change related to the PuraPly products. Specifically, after the proposed rule was published, we became aware that HCPCS code Q4172 (Puraply, and Puraply AM per square centimeter) will be deleted effective January 1, 2019, and will be replaced by three new HCPCS codes: Q4195 (Puraply, per square centimeter); Q4196 (Puraply am, per square centimeter); and Q4197 (Puraply xt, per square centimeter), effective January 1, 2019. Two of these products, PuraPly (HCPCS code Q4195) and PuraPly AM (HCPCS code Q4196), were products that received original pass-through payment status on January 1, 2015, and will continue to receive pass-through payment status in CY 2019 when our finalized policies are implemented.

For January 1, 2019 through March 31, 2019, we are finalizing our proposal that pass-through payment for the covered drugs and biologicals will be the greater of: (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. We also are finalizing our proposal that the pass-through payment amount for these drugs and biologicals will be the amount that applies under section 1833(t)(6)(D)(i) of the Act for the period of April 1, 2019 through December 31, 2019.

We are finalizing our proposal to continue to update pass-through payment rates for these covered drugs and biologicals on a quarterly basis on the CMS website during CY 2019 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs or biologicals are necessary. We refer readers to Table 39 below for the drugs and biologicals covered by the requirements of this section.

TABLE 39.—DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS IN CY 2019 IN ACCORDANCE WITH PUB. L. 115-141

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator	CY 2019 APC	Pass-Through Payment Effective Date
A9586	A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018
C9447	C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
Q4172	Q4195	Puraply, per square centimeter	G	9175	10/01/2018
Q4172	Q4196	Puraply AM, per square centimeter	G	9176	10/01/2018
Q9950	Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulations at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full

description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). In the CY 2019 OPPS/ASC proposed rule (83 FR 37115), for CY 2019, as we did in CY 2018, we proposed to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes were identified in Table 22 of the proposed rule (83 FR 37115).

We did not receive any comments on this proposal. Therefore, we are finalizing this proposal without modification.

TABLE 40.—APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET ARE APPLICABLE IN CY 2019

CY 2019 APC	CY 2019 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

In the CY 2019 OPPS/ASC proposed rule, we proposed to continue to post annually on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC. We did not receive any public comments on our proposal, and therefore are finalizing it without modification.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $120 for CY 2018 (82 FR 59343).

Following the CY 2007 methodology, for this CY 2019 OPPS/ASC final rule with comment period, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2019 and rounded the resulting dollar amount ($127.01) to the nearest $5 increment, which yielded a figure of $125. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary. For this CY 2019 OPPS/ASC final rule with comment period, based on these calculations using the CY 2007 OPPS methodology,

we are finalizing a packaging threshold for CY 2019 of $125.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

In the CY 2019 OPPS/ASC proposed rule (83 FR 37116), to determine the proposed CY 2019 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2017 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2017 claims processed before January 1, 2018 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2019: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2019, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals for CY 2019, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2019 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2017 (data that were used for payment purposes in the physician's office setting, effective April 1, 2018) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2019, we proposed to use payment rates based on the ASP data from the first quarter of CY 2018 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the internet on the CMS website) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2018. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2017 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $125, and identify items with a per day cost greater than $125 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2017 HCPCS codes that were reported to the CY 2018 HCPCS codes that we displayed in Addendum B to the proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2019.

Comment: A few commenters requested that CMS not finalize the proposed increase to the packaging threshold to $125 and suggested that CMS instead lower the packaging threshold. These commenters expressed concern with the annual increases in the drug packaging threshold, citing that yearly increases have outpaced conversion factor updates and place a financial burden on providers.

Response: We have received and addressed similar comments in prior rules, including most recently in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79666). As we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that updating the packaging threshold of $50 for the CY 2005 OPPS is consistent with industry and government practices, and that the PPI for Prescription Drugs is an appropriate mechanism to gauge Part B drug inflation. Therefore, because packaging is a fundamental component of a prospective payment system that continues to provide important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting the commenters' recommendation to delay updating the packaging threshold or freeze the packaging threshold at $120.

After consideration of the public comments we received, and consistent with our methodology for establishing the packaging threshold using the most recent PPI forecast data, we are adopting a CY 2019 packaging threshold of $125.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2019 OPPS/ASC final rule with comment period, we used ASP data from the third quarter of CY 2018, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective July 1, 2018, along with updated hospital claims data from CY 2017. We note that we also used these data for budget neutrality estimates and impact analyses for this CY 2019 OPPS/ASC final rule with comment period.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for this final rule with comment period are based on ASP data from the third quarter of CY 2018. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2018. These payment rates will then be updated in the January 2019 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2019. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2017 claims data and updated cost report information available for this CY 2019 final rule with comment period to determine their final per day cost.

Consequently, as stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37117), the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for this final rule with comment period. Under such circumstances, in the CY 2019 OPPS/ASC proposed rule (83 FR 37117), we proposed to continue to follow the established policies

initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2019 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2018. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2019, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2019 final rule, would continue to receive separate payment in CY 2019.
- HCPCS codes for drugs and biologicals that were packaged in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2019 final rule, would remain packaged in CY 2019.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2019 but that then have per-day costs greater than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for this CY 2019 final rule, would receive separate payment in CY 2019.

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2017 claims data and updated cost report information available for this CY 2019 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2019, we are finalizing these two proposals without modification.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, in the OPPS, we package several categories of drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

We did not make any proposals to revise our policy-packaged drug policy. We solicited public comment on the general OPPS packaging policies as discussed in section II.3.a. of this final rule with comment period.

Comment: One commenter recommended that CMS continue to apply the nuclear medicine procedure to radiolabeled product edits to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used for the procedures in their claims submissions. The commenter believed this lack of drug cost reporting is causing the cost of nuclear medicine procedures to be underreported, and that the radiolabeled product edits will ensure providers are reporting the cost of diagnostic radiopharmaceuticals in their claims data.

Response: We do not agree with the commenter that we should reinstate the nuclear medicine procedure to radiolabeled product edits, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. The edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: Several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. The commenters provided limited data that showed that procedures where diagnostic radiopharmaceuticals are considered to be a surgical supply often are paid at a lower rate than what the payment rate is for the diagnostic radiopharmaceutical itself when the drug is paid separately on pass-through payment status. The commenters stated that diagnostic radiopharmaceuticals are highly complex drugs that undergo a rigorous approval process by the FDA.

The commenters believed that the type of procedure in which a drug or biological is used should not dictate whether that drug or biological is a supply and is packaged.

Response: We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with radiopharmaceuticals should be reported on hospital claims to the extent they are used. Therefore, payment for the radiopharmaceuticals is reflected within the payment for the primary procedure. While at least one commenter provided limited data showing the proposed cost of the packaged procedure in CY 2019 is substantially lower than the cost of the separately paid radiopharmaceutical on pass-through payment plus the cost of the procedure associated with the radiopharmaceutical, we note the rates are established in a manner that takes the average (more specifically, the geometric mean) of reported costs to furnish the procedure based on data submitted to us from all hospitals paid under the OPPS. Accordingly, the costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of items and services because the billing patterns of hospitals may not reflect that a particular item or service is always billed with the primary procedure. Further, the costs will be based on the reported costs submitted to Medicare by hospitals, not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associate procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

d. High Cost/Low Cost Threshold for Packaged Skin Substitutes

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to finalize the packaging of skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described above are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures) (HCPCS codes C5271, C5275, and C5277); APC 5054 (Level 4 Skin Procedures) (HCPCS codes C5273, 15271, 15275, and 15277); or APC 5055 (Level 5 Skin Procedures) (HCPCS code 15273). In CY 2018, the payment rate for APC 5053 (Level 3 Skin Procedures) was $488.20, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,568.43, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,710.48. This information also is available in Addenda A and B of the CY 2018 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and in the CY 2019 OPPS/ASC proposed rule (83 FR 37117), we proposed to continue it for CY 2019. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). For CY 2019, as with our policy since CY 2016, we proposed to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. For CY 2019, as for CY 2018, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, as described in more detail later in this section, for CY 2019, as for CY 2018, we proposed to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2019, we proposed that any skin substitute product that was assigned to the high cost group in CY 2018 would be assigned to the high cost group for CY 2019, regardless of whether it exceeds or falls below the CY 2019 MUC or PDC threshold.

For this CY 2019 OPPS/ASC final rule with comment period, consistent with the methodology as established in the CY 2014 through CY 2017 final rules with comment period, we analyzed updated CY 2017 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The final CY 2019 MUC threshold is $49 per cm^2 (rounded to the nearest $1) (proposed at $49 per cm^2) and the final CY 2019 PDC threshold is $872 (rounded to the nearest $1) (proposed at $895).

For CY 2019, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. We proposed to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we stated in the proposed rule that we would use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We proposed to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of the proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. We also

stated in the proposed rule that new skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2019 MUC threshold. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

Some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: Establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), for CY 2018, we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinement to the existing policies is consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin substitutes and take these comments into consideration for future rulemaking. We received many responses to our requests for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37118 through 37119), we have identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the proposed rule that we are especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market. We also specified in the proposed rule that we are interested in any new ideas that are not represented below along with an analysis of how different skin substitute products would fare under such ideas. We stated that we intend to explore the full array of public comments on these ideas for the CY 2020 rulemaking, and we indicated that we will consider the feedback received in response to our requests for comments in the CY 2019 proposed rule in developing proposals for CY 2020.

- *Establish a lump-sum ''episode-based'' payment for a wound care episode.* Under this option, a hospital would receive a lump sum payment for all wound care services involving procedures using skin substitutes. The payment would be made for a wound care ''episode'' (such as 12 weeks) for one wound. The lump sum payment could be the same for all skin substitutes or could vary based on the estimated number of applications for a given skin substitute during the wound care episode. Under this option, payment to the provider could be made at the start of treatment, or at a different time, and could be made once or split into multiple payments. Quality metrics, such as using the recommended number of treatments for a given skin substitute during a treatment episode, and establishing a plan of care for patients who do not experience 30 percent wound healing after 4 weeks, could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.
- *Eliminate the high cost/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products.* This option would reduce the financial incentives to use expensive skin substitutes and would provide incentives to use less costly skin substitute products that have been shown to have similar efficacy treating wounds as more expensive skin substitute products. A single payment category would likely have a payment rate that is between the current rates paid for high cost and low cost skin substitute procedures. Initially, a single payment category may lead to substantially higher payment for skin graft procedures performed with cheaper skin substitutes as compared to their costs. However, over time, payment for skin graft procedures using skin substitutes might reflect the lower cost of the procedures.
- *Allow for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm^2 and 99 cm^2 and substantially over 100 cm^2.* Under this option, payment for skin substitutes would be made more granularly based on the size of the skin substitute product being applied. This option also would reduce the risk that hospitals may not use enough of a skin substitute to save money when performing a procedure. However, such granularity in the use of skin substitutes could conflict with the goals of a prospective payment system, which is based on a system of averages. Specifically, it is expected that

some skin graft procedures will be less than 25 cm^2 or around 100 cm^2 and will receive higher payments compared to the cost of the services. Conversely, services between 26 cm^2 and 99 cm^2 or those that are substantially larger than 100 cm^2 will receive lower payments compared to the cost of the services, but the payments will average over many skin graft procedures to an appropriate payment rate for the provider.

• *Keep the high cost/low cost skin substitute categories, but change the threshold used to assign skin substitutes in the high cost or low cost group.* Consider using other benchmarks that would establish more stable thresholds for the high cost and low cost groups. Ideas include, but are not limited to, fixing the MUC or PDC threshold at an amount from a prior year, or setting global payment targets for high cost and low cost skin substitutes and establishing a threshold that meets the payment targets. Establishing different thresholds for the high cost and low cost groups could allow for the use of a mix of lower cost and higher cost skin substitute products that acknowledges that a large share of skin substitutes products used by Medicare providers are higher cost products but still providing substantial cost savings for skin graft procedures. Different thresholds may also reduce the number of skin substitute products that switch between the high cost and low cost groups in a given year to give more payment stability for skin substitute products.

Comment: Several commenters supported the four options presented in the CY 2019 OPPS proposed rule (83 FR 37118 through 37119). Other commenters opposed the four options.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to changing the methodology for paying for skin substitute products, and we will take these comments into consideration for CY 2020 rulemaking.

To allow stakeholders time to analyze and comment on the potential ideas raised above, in the CY 2019 OPPS/ASC proposed rule (83 FR 37119), for CY 2019, we proposed to continue our policy established in CY 2018 to assign skin substitutes to the low cost or high cost group. However, for CY 2020, we stated in the proposed rule that we may revise our policy to reflect one of the potential new methodologies discussed above or a new methodology included in public comments in response to the CY 2019 proposed rule. Specifically, for CY 2019, we proposed to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2018, in which case we would assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. We also proposed to assign to the high cost group any skin substitute product that exceeds the CY 2019 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and were not assigned to the high cost group in CY 2018. We proposed to continue to use payment methodologies including ASP+6 percent and 95 percent of AWP for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2019 MUC. In addition, we proposed to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or have claims data to determine if those products' costs exceed the CY 2019 MUC. We also proposed to retain our established policy to assign new skin substitute products with pricing information to the low cost group.

Table 23 in the CY 2019 OPPS/ASC proposed rule (83 FR 37119 through 37120) displayed the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

Comment: Two commenters requested that CMS implement a single skin substitute payment category in CY 2019 rather than keeping the current high cost and low cost categories. The commenters believed that the existence of separate categories for high cost and low cost skin substitutes encourages the over-utilization of high cost skin substitutes which increases program cost for CMS and copayments for beneficiaries.

Response: At this time, we do not believe that establishing one cost category for all skin substitute products is prudent. While several commenters supported a single payment category for skin substitutes as a potential future refinement to the payment policy for these products, several other commenters expressed significant concern about this payment method. Accordingly, we do not believe it would be appropriate to establish such a major payment change in this final rule with comment period without having proposed it.

Comment: A number of commenters supported the proposal to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2018, in which case CMS would assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. These commenters also supported the proposal to assign to the high cost group any skin substitute product that exceeds the CY 2019 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and was not assigned to the high cost group in CY 2018. One of the commenters supported the proposal for CY 2019, but requested that CMS establish new skin substitute payment policy for CY 2020. Another commenter requested that CMS maintain the current payment methodologies for up to 5 years until a new skin substitute payment system is implemented.

Response: We appreciate the support from the commenters for our proposals and their support for developing a new methodology for paying for skin substitute procedures in future rulemaking.

Comment: One commenter expressed appreciation to CMS for assigning HCPCS codes Q4122 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) to the high cost group.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2018, in which case we would assign the product to the high cost group for CY 2019, regardless of whether it exceeds the CY 2019 MUC or PDC threshold. We also are finalizing our proposal to assign to the high cost group any skin substitute product that exceeds the CY 2019 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2019 MUC or PDC thresholds and was not assigned to the high cost group in CY 2018. We are finalizing our proposal to continue to use payment methodologies including ASP+6 percent and 95 percent of AWP for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2019 MUC. In addition, we are finalizing our proposal to use WAC+3 percent instead of WAC+6

percent for skin substitute products that do not have ASP pricing information or claims data to determine if those products' costs exceed the CY 2019 MUC. We also are finalizing our proposal to retain our established policy to assign new skin substitute products with pricing information to the low cost group.

Table 41 below displays the final CY 2019 cost category assignment for each skin substitute product.

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TABLE 41.—SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2019

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
C9363	Integra Meshed Bil Wound Mat	High	High
Q4100	Skin Substitute, NOS	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis Wound Matrix	Low	Low
Q4103	Oasis Burn Matrix	High	High*
Q4104	Integra BMWD	High	High
Q4105	Integra DRT	High	High*
Q4106	Dermagraft	High	High
Q4107	GraftJacket	High	High
Q4108	Integra Matrix	High	High
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis Tri-layer Wound Matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High*
Q4127	Talymed	High	High
Q4128	Flexhd/Allopatchhd/Matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	hMatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence DryFlex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1CM	High	High
Q4147	Architect ecm, 1cm	High	High*
Q4148	Neox neox rt or clarix cord	High	High
Q4150	Allowrap DS or Dry 1 sq cm	High	High

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4151	AmnioBand, Guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest 1 square cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	NuShield 1 square cm	High	High
Q4161	Bio-Connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square cm	Low	Low
Q4167	Truskin, per square cm	Low	Low
Q4169	Artacent wound, per sq cm	High	High*
Q4170	Cygnus, per square cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per square centimeter	Low	Low
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	Low	Low
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High*
Q4182	Transcyte, per sq centimeter	Low	Low
Q4183	Surgigraft, 1 sq cm	Low	Low
Q4184	Cellesta, 1 sq cm	Low	Low
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	Low
Q4190	Artacent ac 1 sq cm	Low	Low
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	Low
Q4194	Novachor 1 sq cm	Low	Low
Q4195+	Puraply 1 sq cm	High	High
Q4196+	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1sqcm	Low	Low
Q4200	Skin te 1 sq cm	Low	Low
Q4201	Matrion 1 sq cm	Low	Low

CY 2019 HCPCS Code	CY 2019 Short Descriptor	CY 2018 High/Low Assignment	CY 2019 High/Low Assignment
Q4203	Derma-gide, 1 sq cm	Low	Low
Q4204	Xwrap 1 sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2019, but are assigned to the high cost group because they were assigned to the high cost group in CY 2018.
+ Pass-through payment status in CY 2019.

e. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believed that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37121), we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2019.

For CY 2019, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2017 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for the CY 2019 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2017 claims data to make the proposed packaging determinations for these drugs: HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1,000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2019 drug packaging threshold of $125 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2019 drug packaging threshold of $125 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2019 was displayed in Table 24 of the CY 2019 OPPS/ASC proposed rule (83 FR 37121).

We did not receive any public comments on this proposal. Therefore, for CY 2019, we are finalizing our CY 2019 proposal, without modification, to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. Table 42 below displays the final packaging status of each drug and biological HCPCS code to which the finalized methodology applies for CY 2019.

TABLE 42.—HCPCS CODES TO WHICH THE CY 2019 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2019 HCPCS Code	CY 2019 Long Descriptor	CY 2019 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J1840	Injection, kanamycin sulfate, up to 500 mg	N
J1850	Injection, kanamycin sulfate, up to 75 mg	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[57]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2019 OPPS/ASC proposed rule (83 FR 37122), we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2018.

Comment: One commenter requested that HCPCS code J0476 (Injection, baclofen, 50 mcg for intrathecal trial) be separately payable in CY 2019 and be assigned status indicator ''K'' (Paid under OPPS; separate APC payment).

Response: The per day cost of the drug described by HCPCS code J0476 is less than the drug packaging threshold amount of $125. Therefore, the drug described by HCPCS code J0476 will be packaged into the cost of the related services for CY 2019.

Comment: One commenter supported the assignment of GenVisc 850, described by HCPCS code J7320, to a separately payable status with status indicator ''K'' (Paid under OPPS; separate APC payment) for CY 2019. The commenter also requested that TriVisc, described by HCPCS code J7329, also be assigned to a separately payable status for CY 2019.

Response: We appreciate the commenter's support. For HCPCS code J7329, we are not able to assign the code to a payable status because no pricing information is available for the code. If pricing information becomes available prior to the next rulemaking cycle, we would expect to assign a payable status in a quarterly update to the OPPS.

b. CY 2019 Payment Policy

In the CY 2019 OPPS/ASC proposed rule (83 FR 37122), for CY 2019, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to continue to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent. We refer readers to section V.A.7. of the proposed rule and this final rule with comment period for more information about how the payment rate for drugs acquired with a 340B discount was established.

In the case of a drug or biological during an initial sales period in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II), the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS proposed rule, under section 1847A(c)(4), although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that certain payments must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular

[57] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

add-on amount be applied to partial quarter WAC-based pricing. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS proposed rule, we proposed that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act would utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used per our policy in effect as of CY 2018. For the OPPS, in the CY 2019 OPPS/ASC proposed rule (83 FR 37122), we also proposed to utilize a 3 percent add-on instead of a 6 percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We proposed that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological. We stated in the proposed rule that for drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate (in this case, WAC minus 22.5 percent) would continue to apply. We referred readers to the CY 2019 PFS proposed rule for additional background on this anticipated proposal.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed that payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also proposed that the budget neutral weight scalar not be applied in determining payments for these separately paid drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this final rule with comment period (available via the internet on the CMS website), which illustrate the final CY 2019 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective October 1, 2018, or WAC, AWP, or mean unit cost from CY 2017 claims data and updated cost report information available for this final rule with comment period. In general, these published payment rates are not the same as the actual January 2019 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2019 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2018 (July 1, 2018 through September 30, 2018) will be used to set the payment rates that are released for the quarter beginning in January 2019 near the end of December 2018. In addition, payment rates for drugs and biologicals in Addenda A and B to this final rule with comment period for which there was no ASP information available for October 2018 are based on mean unit cost in the available CY 2017 claims data. If ASP information becomes available for payment for the quarter beginning in January 2019, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for this final rule with comment period (reflecting October 2018 ASP data) that do not have ASP information available for the quarter beginning in January 2019. As stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), these drugs and biologicals will then be paid based on mean unit cost data derived from CY 2017 hospital claims. Therefore, the payment rates listed in Addenda A and B to this final rule with comment period are not for January 2019 payment purposes and are only illustrative of the CY 2019 OPPS payment methodology using the most recently available information at the time of issuance of this final rule with comment period.

Comment: A number of commenters supported CMS' proposal to continue to pay for separately payable drugs and biologicals based on the statutory default rate of ASP+6 percent.

Response: We appreciate the commenters' support.

Comment: Several commenters supported the proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act, pursuant to CMS' authority under section 1833(t)(14)(A)(iii)(II) of the Act. These commenters recommended this as a first step to lowering drug costs for beneficiaries and the Medicare Program as well as removing the financial incentive associated with a specific prescribing choice. The commenters suggested modifying the add-on to be a flat fee.

Response: We appreciate the commenters' support. We proposed a fixed percentage, instead of a flat fee, in order to be consistent with other provisions in section 1847A of the Act that specify fixed add-on percentages of 6 percent (section 1847A(b) of the Act) or 3 percent (section 1847A(d)(3)(C) of the Act). A fixed percentage is also administratively simple to implement and administer, is predictable, and is easy for manufacturers, providers and the public to understand.

Comment: Many commenters opposed the proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act. Several commenters were concerned that paying less for new drugs may discourage the use of innovative drugs due to concerns about decreased payment, especially with the sequestration cuts decreasing the payment further. The commenters also were concerned that the proposal would only affect payment to the provider, and would not address pricing on the pharmaceutical manufacturer side. The commenters requested additional studies to analyze the appropriateness and accuracy of the 3 percent reduction, and encouraged additional modifications to ASP reporting, such as requiring all Part B drug manufacturers to report pricing information and for all Part B drugs to be included in the ASP quarterly update file.

Response: We appreciate these comments. The implementation of these proposals will improve Medicare payment rates by better aligning payments with drug acquisition costs, which is of great importance to CMS because spending on Part B drugs has grown significantly. A WAC+3 percent add-on is more comparable to an ASP+6 percent add-on, as the WAC pricing does not reflect many of the discounts associated with ASP, such as rebates. The utilization of a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act is consistent with MedPAC's analysis and recommendations cited in its June 2017 Report to the Congress, and as discussed in the CY 2019 PFS proposed rule (83 FR 35854 through 35855). Overall, this policy still represents a net payment greater than the WAC. In addition, this policy decreases beneficiary cost-sharing for these drugs, which would help Medicare beneficiaries afford to pay for new drugs by reducing out-of-pocket expenses.

Comment: Some commenters did not support the inclusion of radiopharmaceuticals in the proposal to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC. The commenters cited pharmacy overhead and handling costs for radiopharmaceuticals, pointed out that these costs are higher than for any other class of drugs, and suggested an increased payment rate. In addition, the commenters were concerned that this reduction would disproportionately affect the pass-through payments for diagnostic radiopharmaceuticals.

Response: We appreciate these comments. We recognize that radiopharmaceuticals tend to utilize the WAC-based payment methodology more compared to other products. However, no significant evidence has been presented to substantiate that a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC would negatively affect access, including during the pass-through payment status period, if applicable. We received limited current data from commenters to justify the exclusion of radiopharmaceuticals from this proposal.

Comment: Several commenters made recommendations to exclude certain drugs and biologicals from this proposal, including skin substitutes and biosimilar biological products. The commenters were concerned about skin substitutes being assigned to the high- or low-cost category when ASP data are not available based on a WAC+3 percent methodology compared to a WAC+6 percent methodology. The commenters recommended maintaining payment for biosimilars at WAC+6 percent to encourage the increase in utilization of biosimilars.

Response: We appreciate these comments. However, use of a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act is consistent with MedPAC's analysis and recommendations cited in its June 2017 Report to the Congress, and as discussed in the CY 2019 PFS proposed rule (83 FR 35854 through 35855). This policy is not meant to give preferential treatment to any drugs or biologicals.

Comment: Commenters were concerned about coverage for drugs that are not included in the ASP Quarterly Update File being paid at WAC+3 percent instead of the current rate of ASP+6 percent. For example, the commenters were concerned that OTIPRIO (HCPCS code J7342), a drug that is not included in the ASP Quarterly Update File, will not be paid at ASP+6 percent, and would be paid at WAC+3 percent. In addition, the commenters requested clarification regarding MAC payment for drugs that fall under sections 1847A(c)(4) and 1847A(b)(1) of the Act.

Response: Drugs that are not included in the ASP Quarterly Update File will continue to be paid at their current rate of ASP+6 percent as long as the manufacturer continues to submit ASP information to CMS on a timely basis and assuming the drug is not packaged.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: All biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP+6 percent of the reference product's ASP.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the current payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also believed this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired

under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP.

Comment: Many commenters supported CMS' proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. The commenters stated that this proposal would ensure fair access to biosimilar treatments.

Response: We appreciate the commenters' support. We believe this proposal appropriately reflects the resources and production costs that manufacturers incur, as well as more closely aligns with the hospitals' acquisition costs for these products.

Comment: Several commenters supported CMS' proposal to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenters stated that this proposal would continue to lower costs and improve access to treatments.

Response: We appreciate the commenters' support.

Comment: Some commenters recommended eliminating the proposal to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenters believed this policy could potentially encourage inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment.

Response: We are not convinced that making all biosimilar biological products eligible for pass-through payment will lead to inappropriate treatment changes from a reference product without pass-through payment to a biosimilar product with pass-through payment. Eligibility for pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals.

After consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also are finalizing our proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2019. Therefore, we proposed for CY 2019 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2017 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2019 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Comment: Commenters supported continuation of the policy to pay ASP+6 percent for therapeutic radiopharmaceuticals, if available, and to base payment on the mean unit cost derived from hospital claims data when not available. The commenters also requested that CMS examine ways to compensate hospitals for their documented higher overhead and handling costs associated with radiopharmaceuticals.

Response: We appreciate the commenters' support. However, as we stated earlier in section V.B.1.c. of this final rule with comment period in response to a similar request for additional radiopharmaceutical payment and as previously stated in the CY 2018 OPPS final rule with comment period (82 FR 59352), we continue to believe that a single payment is appropriate for radiopharmaceuticals with pass-through payment status in CY 2019 and that the payment rate of ASP+6 percent is appropriate to provide payment for both the radiopharmaceutical's acquisition cost and any associated nuclear medicine handling and compounding costs incurred by the hospital pharmacy. Payment for the radiopharmaceutical and radiopharmaceutical processing services is made through the single ASP-based payment. We refer readers to the CMS guidance document available via the internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Archives.html* for details on submission of ASP data for therapeutic radiopharmaceuticals.

Comment: One commenter asked CMS to clarify the payment rate reported for APC 1675, P32 Na phosphate (HCPCS code A9563), which is based on geometric mean unit cost. The commenter stated that, in the proposed rule, the payment rate for HCPCS code A9563 was reported as $256.00, but the mean unit cost for the radiopharmaceutical as reported in data files accompanying the proposed rule was $519.21.

Response: We thank the commenter for bringing this reporting error to our attention. We are providing a corrected payment rate for APC 1675, P32 Na

phosphate (HCPCS code A9563) in Addenda A and B of this final rule with comment period (which is available via the internet on the CMS website).

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We also are finalizing our proposal to continue to rely on CY 2017 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2019 final payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

4. Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation is that this additional payment will be needed for the duration of the industry's conversion to alternative methods to producing Tc-99m without HEU. We also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68316). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipates the conversion of Tc-99m production from non-HEU sources will not be complete until the end of 2019.[58] In addition, one of the manufacturers of Tc-99m generators sent a letter to CMS to support continuing the payment adjustment at the current level because only 30 percent of Tc-99m is produced from non-HEU sources. We also met with a trade group of nuclear pharmacies and cyclotron operators who support an increase in the payment adjustment by the rate of inflation to cover more of the cost of Tc-99m from non-HEU sources.

We appreciate the feedback from stakeholders. However, as stated in the CY 2019 OPPS/ASC proposed rule, we continue to believe that the current adjustment is sufficient for the reasons we have outlined in this and prior rulemakings. The information from stakeholders and the National Academies of Sciences, Engineering, and Medicine indicates that the conversion of the production of Tc-99m from non-HEU sources may take more than 1 year after CY 2018. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37124), for CY 2019 and subsequent years, we proposed to continue to provide an additional $10 payment for radioisotopes produced by non-HEU sources. We noted in the proposed rule our intention to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.

Comment: Several commenters requested that the additional payment for radioisotopes produced by non-HEU sources be increased to either $30 or $10 plus the percentage increase in hospital charge data for APC 1442 for the period of 2014 through 2019, which appears to be a request from the commenter to increase the payment by the rate of hospital inflation. One of the commenters supported this request by supplying provider cost data showing the cost difference between HEU Mo-99 and non-HEU Mo-99 in 2017 per curie was around $30.

One commenter requested that CMS provide an explanation for not applying an annual inflation update to the $10 payment for radioisotopes produced by non-HEU sources, provide details on plans to offset nuclear medicine procedures by the amount of cost paid through the non-HEU policy, and make available to the public data regarding the claims submitted to date under this policy. The commenter also stated that CMS should assess whether the beneficiary copayment policy is adversely impacting patient access.

Response: We appreciate the information we received from stakeholders supporting an increase to the payment rate of $10 for HCPCS code Q9969. As we stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68317), ''The purpose for the additional payment is limited to mitigating any adverse impact of existing payment policy and is based on the authority set forth at section 1833(t)(2)(E) of the Act.'' However, we are open to further study of this issue and are interested in exploring whether a higher add-on payment, such as $30, may be warranted for a future year. We invite stakeholders to continue to submit data and evidence for further consideration as we continue to evaluate this policy. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose of the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources and is based on the authority set forth at section 1833(t)(2)(E) of the Act. Therefore, we will maintain the current payment rate of $10.

With respect to the comment that we should assess whether the beneficiary copayment amount is adversely affecting patient access, we will consider the commenter's concern. However, we note that increasing the add-on payment from the current level as the commenter suggested would necessarily increase the beneficiary copayment liability. Finally, the offset for nuclear medicine procedures does not include the cost of the non-HEU add-on payment.

Comment: One commenter requested that CMS provide detailed data on hospital costs associated with radiopharmaceuticals reported with HCPCS code Q9969.

Response: It is unclear what specific data this commenter is seeking that are not already available through public use

[58] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563.*

files. We note that, in 2017, HCPCS code Q9969 was billed 34,439 times and is commonly reported with Level II HCPCS codes A9500 (Technetium tc-99m sestamibi, diagnostic, per study dose) and A9503 (Technetium tc-99m medronate, diagnostic, per study dose, up to 30 millicuries). The geometric mean costs of this and all Level II HCPCS drug codes, including radiopharmaceutical drug codes, can be found in the cost statistics file that is released with this final rule with comment period.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2019 and subsequent years. We will reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.

5. Payment for Blood Clotting Factors

For CY 2018, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (82 FR 59353). That is, for CY 2018, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2018 updated furnishing fee was $0.215 per unit.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37124), for CY 2019, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update was based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we were not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

Comment: Commenters supported CMS' proposal to continue to pay for blood clotting factors at ASP+6 percent plus a blood clotting factor furnishing fee in the hospital outpatient department.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

6. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue to use the same payment policy as in CY 2018 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2019 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data was listed in Addendum B to the proposed rule, which is available via the internet on the CMS website.

We did not receive any comments on our proposal. Therefore, we are finalizing our CY 2019 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2019 if pricing information becomes available. The CY 2019 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the internet on the CMS website.

7. CY 2019 OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the Medicare Part B drug payment methodology for 340B hospitals. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We believed that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP)+6 percent to ASP minus 22.5 percent. Our goal is to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not included in this 340B policy change because they are paid under section 1834(g) of the Act. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs on pass-through payment status, which are required to be paid based on the ASP methodology, or

vaccines, which are excluded from the 340B Program.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37125), another topic that has been brought to our attention since we finalized the payment adjustment for 340B-acquired drugs in the CY 2018 OPPS/ASC final rule with comment period is whether drugs that do not have ASP pricing but instead receive WAC or AWP pricing are subject to the 340B payment adjustment. We did not receive public comments on this topic in response to the CY 2018 OPPS/ASC proposed rule. However, we have since heard from stakeholders that there has been some confusion about this issue. We clarified in the CY 2019 proposed rule that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent and AWP-priced drugs have a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small—consisting of less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

Furthermore, data limitations previously inhibited our ability to identify which drugs were acquired under the 340B Program in the Medicare OPPS claims data. This lack of information within the claims data has limited researchers' and our ability to precisely analyze differences in acquisition cost of 340B and non-340B acquired drugs with Medicare claims data. Accordingly, in the CY 2018 OPPS/ASC proposed rule (82 FR 33633), we stated our intent to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were not acquired under the 340B Program. Because a significant portion of hospitals paid under the OPPS participate in the 340B Program, we stated our belief that it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B Program, unless the hospital identifies that the drug was not purchased under the 340B Program. We stated in the CY 2018 proposed rule that we intended to provide further details about this modifier in the CY 2018 OPPS/ASC final rule with comment period and/or through subregulatory guidance, including guidance related to billing for dually eligible beneficiaries (that is, beneficiaries covered under Medicare and Medicaid) for whom covered entities do not receive a discount under the 340B Program. As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals or those hospitals paid under the Maryland waiver), or excepted from the 340B drug payment policy for CY 2018, are required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals are required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent.

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifier ''JG''.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37125), for CY 2019, we proposed to continue the 340B Program policies that were implemented in CY 2018 with the exception of the way we calculate payment for 340B-acquired biosimilars (that is, we proposed to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP). More information on our revised policy for the payment of biosimilars acquired through the 340B Program is available in section V.B.2.c. of this final rule. We proposed, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs (assigned status indicator ''K''), other than vaccines and drugs on pass-through payment status, that meet the definition of ''covered outpatient drug'' as defined in section 1927(k) of the Act, that are acquired through the 340B Program at ASP minus 22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs with OPPS transitional pass-through payment status (assigned status indicator ''G''). As discussed in section V.B.2.c. of the proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. We also proposed that Medicare would continue to pay for drugs or biologicals that were not purchased with a 340B discount at ASP+6 percent.

As stated earlier, to effectuate the payment adjustment for 340B-acquired drugs, CMS implemented modifier ''JG'', effective January 1, 2018. For CY 2019, we proposed that hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS, or excepted from the 340B drug payment policy for CY 2018, continue to be required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. We also proposed for CY 2019 that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from the 340B payment adjustment. We proposed that these hospitals be required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent.

Comment: One commenter supported the proposal to continue to pay for separately payable drugs and biologicals obtained through the 340B program at ASP minus 22.5 percent. The commenter believed the payment rate of ASP minus 22.5 percent will help CMS address the large amount of growth in the 340B Program by increasing oversight and promoting the integrity of the program.

Another commenter, MedPAC, also supported the proposal. MedPAC believed a lower payment rate allows beneficiaries to share in the savings from the 340B Program, better targets resources to hospitals providing the most uncompensated care, and still allows 340B hospitals to make a profit off the drugs obtained through the program. MedPAC preferred that the payment rate be ASP+6 percent minus a 10 percent discount with the savings assigned to a Medicare-funded uncompensated care pool, but noted that this policy requires Congressional action.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed the CY 2019 proposal to continue to pay for separately payable drugs and biologicals obtained through the 340B Program at ASP minus 22.5 percent. Many commenters stated that the new payment rate has hurt hospitals financially and has hurt efforts by hospitals to provide safety-net care to their patients. The commenters were also concerned about the same service costing more at non-340B hospitals than at hospitals enrolled in the 340B Program because drugs furnished at a non-340B hospital would be paid at ASP+6 percent while drugs furnished at a 340B hospital would be paid at ASP minus 22.5 percent. One commenter whose hospital provides cancer treatment stated the reductions in 340B payment mean the hospital cannot provide the broader cancer care options available at non-340B hospitals. Commenters also stated that reducing payment for drugs acquired through the 340B Program does not help reduce high drug costs. Many commenters asserted, as they have previously done, that CMS does not have the legal authority to implement payment reductions for drugs and biologicals obtained through the 340B Program. The commenters requested that CMS end its policy of paying for drugs obtained through the 340B program at ASP minus 22.5 percent. Instead, the commenters suggested that CMS go back to the payment policy that was in place before CY 2018 where drugs acquired through the 340B Program were paid at ASP+6 percent.

Response: The commenters stated that the payment rate of ASP minus 22.5 percent for drugs and biologicals has caused financial harm to hospitals and has caused problems for hospitals to provide safety-net care to their patients. We noted in the CY 2018 final rule with comment period (82 FR 59358 through 59359) that the OPPS payment rate of ASP+6 percent at that time significantly exceeded the discounts received for covered outpatient drugs by hospitals enrolled in the 340B Program, which can be as much as 50 percent below ASP (or higher through the PVP). As stated throughout that section, ASP minus 22.5 percent represents the average minimum discount that 340B enrolled hospitals paid under the OPPS receive.

Regarding the concerns of the commenters that drugs and biologicals and services where drugs and biologicals are packaged into the cost of the service would cost more at hospitals that do not participate in the 340B Program as compared to hospitals participating in the 340B Program, any differential in these costs is a feature of the 340B Program rather than Medicare payment policy. In fact, one of the objectives of our payment policy for drugs and biologicals acquired through the 340B Program is to lower costs for Medicare beneficiaries, and we believe it is appropriate that hospitals participating in the 340B Program pass the cost savings they receive to their beneficiaries.

Finally, regarding the commenters' assertion that CMS lacks the legal authority to continue requiring payment reductions for drugs and biologicals obtained through the 340B Program, we refer these commenters to our detailed response regarding our statutory authority to require payment reductions for drugs and biologicals obtained through the 340B Program in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59359 through 59364).

After consideration of the public comments we received, we are finalizing our proposals without modification. For CY 2019, we are continuing the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of this final rule with comment period. We refer readers to the CY 2018 final rule with comment period (82 FR 59369 through 59370) for more detail on the policies implemented in CY 2018 for drugs acquired through the 340B Program.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro-rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing an estimate of pass-through spending in CY 2019 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2019. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2018 or beginning in CY 2019. The sum of the CY 2019 pass-through spending estimates for these two groups of device categories equals the total CY 2019 pass-through spending estimate for device categories with pass-through payment status. We base the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the CY 2019 OPPS/ASC proposed rule (83 FR 37126), we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2019, we

also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our estimate of drug and biological pass-through payment for CY 2019 for this group of items is $0, as discussed below, because we proposed to pay for most nonpass-through separately payable drugs and biologicals under the CY 2019 OPPS at ASP+6 percent (with the exception of 340B-acquired separately payable drugs, for which we do not yet have sufficient data to estimate a share of total drug payments), and because we proposed to pay for CY 2019 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of the proposed rule and this final rule with comment period.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section II.A.3. of the proposed rule and this final rule with comment period. In the CY 2019 OPPS/ASC proposed rule (83 FR 37126), we proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2019. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2019 was not $0, as discussed below. In section V.A.5. of the proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2019. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible in the remaining quarters of CY 2018 or beginning in CY 2019. The sum of the CY 2019 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2019 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2019 OPPS/ASC proposed rule (83 FR 37127), we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2019, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2018 (82 FR 59371 through 59373).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2019, there are no active categories for CY 2019. Because there are no active device categories for CY 2019, we proposed an estimate for the first group of devices of $0. We did not receive any public comments on the proposal. Therefore, we are finalizing the proposed estimate for the first group of devices of $0 for CY 2019.

In estimating our proposed CY 2019 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2019; additional device categories that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2019; and contingent projections for new device categories established in the second through fourth quarters of CY 2019. In the CY 2019 OPPS/ASC proposed rule (83 FR 37127), we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For the proposed rule, the estimate of CY 2019 pass-through spending for this second group of device categories was $10 million.

We did not receive any public comments on this proposal. As stated earlier in this final rule with comment period, we have decided to approve one device to receive pass-through status, the remedē® System Transvenous Neurostimulator. The manufacturer of the remedē® System provided utilization data that indicate the spending for the device would be approximately $2.5 million. However, it is possible that additional new devices may receive pass-through payment status during CY 2019, which would lead to the higher pass-through spending for new devices closer to our proposed estimate of $10 million. Therefore, we are finalizing the proposed estimate for this second group of devices of $10 million for CY 2019.

To estimate proposed CY 2019 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for CY 2019, we proposed to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2019 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test

or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2019, we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for nonpass-through drugs and biologicals that will be separately paid at ASP+6 percent, which is zero for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2019 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. For the proposed rule, using the proposed methodology described above, we calculated a CY 2019 proposed spending estimate for this first group of drugs and biologicals of approximately $61.5 million.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated a CY 2019 spending estimate for this first group of drugs and biologicals of approximately $50.9 million.

To estimate proposed CY 2019 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule were newly eligible for pass-through payment in CY 2019, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2018, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2019), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2019 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2019 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $55.2 million.

We did not receive any public comments on our proposal. Therefore, for CY 2019, we are continuing to use the general methodology described above. For this final rule with comment period, we calculated a CY 2019 spending estimate for this second group of drugs and biologicals of approximately $39.9 million.

In summary, in accordance with the methodology described earlier in this section, for this final rule with comment period, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2019 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2019 is approximately $100.8 million (approximately $10 million for device categories and approximately $90.8 million for drugs and biologicals) which represents 0.14 percent of total projected OPPS payments for CY 2019 (approximately $74 billion). Therefore, we estimate that pass-through spending in CY 2019 will not amount to 2.0 percent of total projected OPPS CY 2019 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

In the CY 2019 OPPS/ASC proposed rule (83 FR 37128), for CY 2019, we proposed to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue and did not propose any change to our payment policy for critical care services for CY 2019. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2019 OPPS/ASC proposed rule, we sought public comments on any changes to these codes that we should consider for future rulemaking cycles. We continue to encourage commenters to provide the data and analysis necessary to justify any suggested changes.

We did not receive any public comments on our proposals to continue our current clinic and ED hospital outpatient visits payment policies and our current critical care services payment policies. Therefore, we are adopting these proposals as final without modification.

In section X.V. of the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), for 2019, we proposed a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). For a full discussion of the proposal as well as the comment solicitation on potential methods to control for unnecessary increases in the volume of covered outpatient department services, we refer readers to section X.B. of this final rule with comment period.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized

intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the outpatient department (OPD) services to be covered under the OPPS. The Medicare regulations that implement this provision specify, at 42 CFR 419.21, that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as Medicare Part B services furnished to hospital outpatients designated by the Secretary, which include partial hospitalization services (65 FR 18444 through 18445).

Section 1833(t)(2)(C) of the Act requires the Secretary, in part, to establish relative payment weights for covered OPD services (and any groups of such services described in section 1833(t)(2)(B) of the Act) based on median (or, at the election of the Secretary, mean) hospital costs using data on claims from 1996 and data from the most recent available cost reports. In pertinent part, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we have developed the PHP APCs. Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, we established a per diem payment methodology for the PHP APCs, effective for services furnished on or after July 1, 2000 (65 FR 18452 through 18455). Under this methodology, the median per diem costs were used to calculate the relative payment weights for the PHP APCs. Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

We began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In that final rule with comment period, we made two refinements to the methodology for computing the PHP median: The first remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers; and the second refined our methodology for computing the PHP median per diem cost by computing a separate per diem cost for each day rather than for each bill.

In CY 2009, we implemented several regulatory, policy, and payment changes, including a two-tier payment approach for partial hospitalization services under which we paid one amount for days with 3 services under PHP APC 0172 (Level 1 Partial Hospitalization) and a higher amount for days with 4 or more services under PHP APC 0173 (Level 2 Partial Hospitalization) (73 FR 68688 through 68693). We also finalized our policy to deny payment for any PHP claims submitted for days when fewer than 3 units of therapeutic services are provided (73 FR 68694). Furthermore, for CY 2009, we revised the regulations at 42 CFR 410.43 to codify existing basic PHP patient eligibility criteria and to add a reference to current physician certification requirements under 42 CFR 424.24 to conform our regulations to our longstanding policy (73 FR 68694 through 68695). We also revised the partial hospitalization benefit to include several coding updates (73 FR 68695 through 68697).

For CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based. We used only hospital-based PHP data because we were concerned about further reducing both PHP APC per diem payment rates without knowing the impact of the policy and payment changes we made in CY 2009. Because of the 2-year lag between data collection and rulemaking, the changes we made in CY 2009 were reflected for the first time in the claims data that we used to determine payment rates for the CY 2011 rulemaking (74 FR 60556 through 60559).

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 (for Level 1 services) and APC 0173 (for Level 2 services)) and two for hospital-based PHPs (APC 0175 (for Level 1 services) and 0176 (for Level 2 services)), based on each provider type's own unique data. For CY 2011, we also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates based solely on CMHC data. Under the transition methodology, CMHC APCs Level 1 and Level 2 per diem costs were calculated by taking 50 percent of the difference between the CY 2010 final hospital-based PHP median costs and the CY 2011 final CMHC median costs and then adding that number to the CY 2011 final CMHC median costs. A 2-year transition under this methodology moved us in the direction of our goal, which is to pay appropriately for partial hospitalization services based on each provider type's data, while at the same time allowing providers time to adjust their business operations and protect access to care for Medicare beneficiaries. We also stated that we would review and analyze the data during the CY 2012 rulemaking cycle and, based on these analyses, we might further refine the payment mechanism. We refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994) for a full discussion.

In addition, in accordance with section 1301(b) of the Health Care and Education Reconciliation Act of 2010 (HCERA 2010), we amended the description of a PHP in our regulations to specify that a PHP must be a distinct and organized intensive ambulatory treatment program offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. In accordance with section 1301(a) of HCERA 2010, we revised the definition of a CMHC in the regulations to conform to the revised definition now set forth under section 1861(ff)(3)(B) of the Act (75 FR 71990).

For CY 2012, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74348 through 74352), we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. We established these four PHP APC per diem payment rates based on geometric mean cost levels calculated using the most recent claims and cost data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC

final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622), we solicited comments on possible future initiatives that may help to ensure the long-term stability of PHPs and further improve the accuracy of payment for PHP services, but proposed no changes. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75050 through 75053), we summarized the comments received on those possible future initiatives. We also continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050).

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on PHP APC geometric mean per diem costs, using the most recent claims and cost data for each provider type.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70465), we described our extensive analysis of the claims and cost data and ratesetting methodology. We found aberrant data from some hospital-based PHP providers that were not captured using the existing OPPS ±3 standard deviation trims for extreme cost-to-charge ratios (CCRs) and excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. Consequently, we implemented a trim to remove hospital-based PHP service days that use a CCR that was greater than 5 to calculate costs for at least one of their component services, and a trim on CMHCs with a geometric mean cost per day that is above or below 2 (±2) standard deviations from the mean. We stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456) that, without using a trimming process, the data from these providers would inappropriately skew the geometric mean per diem cost for Level 2 CMHC services.

In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70459 through 70460), we corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers. We corrected the cost inversion with an equitable adjustment to the actual geometric mean per diem costs by increasing the Level 2 hospital-based PHP APC geometric mean per diem costs and decreasing the Level 1 hospital-based PHP APC geometric mean per diem costs by the same factor, to result in a percentage difference equal to the average percent difference between the hospital-based Level 1 PHP APC and the Level 2 PHP APC for partial hospitalization services from CY 2013 through CY 2015.

Finally, we renumbered the PHP APCs, which were previously 0172, 0173, 0175, and 0176, to 5851, 5852, 5861, and 5862, respectively. For a detailed discussion of the PHP ratesetting process, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70467).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, we finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and to combine the Level 1 and Level 2 APCs for hospital-based PHPs because we believed this would best reflect actual geometric mean per diem costs going forward, provide more predictable per diem costs, particularly given the small number of CMHCs, and generate more appropriate payments for these services, for example by avoiding the cost inversions for hospital-based PHPs addressed in the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70459 and 81 FR 79682). We implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities by limiting the impact of inflated CMHC charges on outlier payments. We will continue to monitor the trends in outlier payments and consider policy adjustments as necessary.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59373 through 59381), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. We continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

B. PHP APC Update for CY 2019

1. PHP APC Geometric Mean per Diem Costs

For CY 2019, in the CY 2019 OPPS/ASC proposed rule (83 FR 37130), we proposed to continue to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. Specifically, we proposed to continue to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)). We proposed to continue to calculate the geometric mean per diem costs for CY 2019 for APC 5853 for CMHCs using only CY 2017 CMHC claims data and the most recent CMHC cost data, and the CY 2019 geometric mean per diem costs for APC 5863 for hospital-based PHPs using only CY 2017 hospital-based PHP claims data and the most recent hospital cost data.

We summarize the public comments we received related to these PHP proposals and methodology and include our responses in the sections below focused on CMHC ratesetting and on hospital-based PHP ratesetting in this CY 2019 OPPS/ASC final rule with comment period.

2. Development of the PHP APC Geometric Mean per Diem Costs

In the CY 2019 OPPS/ASC proposed rule (83 FR 37130), for CY 2019 and subsequent years, we proposed to follow the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to determine the PHP APCs' geometric mean per diem costs and to calculate the payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing 3 or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing 3 or more services.

The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC per diem costs, after applying the OPPS budget neutrality adjustments described in section II.A.4. of this final rule with comment period.

As previously stated, in the CY 2019 OPPS/ASC proposed rule, we proposed to apply our established methodologies in developing the CY 2019 geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR greater than 5 hospital service day trim for hospital-based PHP providers. These two trims were finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70455 through 70462) for CY 2016 and subsequent years.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2019 final rule with comment period, prior to calculating the final geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting is not skewed by providers with extreme data. For this CY 2019 OPPS/ASC final rule with comment period, we used the same data preparation steps. Before any trims or exclusions were applied, there were 45 CMHCs in the final PHP claims data file (compared to 44 in the CY 2019 OPPS/ASC proposed rule). Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. By applying this trim for CY 2019 ratesetting, in this final rule with comment period, we excluded 4 CMHCs with geometric mean costs per day below the trim's lower limit of $49.86 and 2 CMHCs with geometric mean costs per day above the trim's upper limit of $293.60. This standard deviation trim removed 6 providers from the ratesetting whose overall effect on the data would have skewed downward the calculation of the final geometric mean per diem costs for CMHCs.

In accordance with our PHP ratesetting methodology, as stated in the proposed rule, we also remove service days with no wage index values, because we use the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation (80 FR 70465). For this CY 2019 final rule with comment period ratesetting, 1 CMHC was missing wage index data for all of its service days and was excluded.

In addition to our trims and data exclusions, before determining the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR greater than 1 to the statewide hospital CCR (80 FR 70457). For this CY 2019 final rule with comment period ratesetting, we identified 3 CMHCs that had CCRs greater than 1. These CMHCs' CCRs were 1.053, 1.009, and 1.025, and each was defaulted to its appropriate statewide hospital CCR for CY 2019 ratesetting purposes.

In summary, these data preparation steps adjusted the CCR for 3 CMHCs by defaulting to the appropriate statewide hospital CCR and excluded 7 CMHCs, resulting in the inclusion of a total of 38 CMHCs (45 total—7 excluded) in our CY 2019 final rule with comment period ratesetting modeling (compared to a total of 36 CMHCs in our modeling in the CY 2019 OPPS/ASC proposed rule). The ±2 standard deviation trim and the exclusion for missing wage index data removed 425 CMHC claims out of a total of 14,431 CMHC claims, resulting in 14,006 CMHC claims used for ratesetting purposes. We believe that excluding providers with extremely low or high geometric mean costs per day or extremely low or high CCRs protects CMHCs from having that data inappropriately skew the calculation of the CMHC APC geometric mean per diem cost.

After applying all of the above trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691) to calculate the final PHP APC geometric mean per diem cost.[59] The final CY 2019 geometric mean per diem cost for all CMHCs for providing 3 or more services per day (CMHC PHP APC 5853) is $121.62 (compared to the proposed geometric mean per diem cost of $119.51).

Below we summarize the public comments we received on our proposals related to continuing to follow our existing CMHC ratesetting methodology and the calculation of the CMHC geometric mean per diem costs.

Comment: Two commenters objected to the continuation of separate APCs by provider type for CY 2019, stating that CMHCs and hospital-based PHPs provide the same services and follow the same regulations, but CMHCs provide them for less costs. One commenter acknowledged that hospitals have higher cost structures, which the commenter asserted was due to hospitals' higher overhead allocation, but believed that CMHCs are being punished for providing more cost-effective and more intensive services.

Response: We disagree that CMHCs are being punished for providing more cost-effective and more intensive services. The difference in payment between CMHCs and hospital-based PHPs reflects differences in resource use. When Congress required the Secretary to implement a hospital outpatient prospective payment system, it required the payment system to group covered services with respect to clinical similarity and resource use (section 1833(t)(2) of the Act). Because CMHCs' and hospital-based PHPs' resource uses are different, these two provider types are paid under different APCs, based on their actual resource use.

Because the cost of providing partial hospitalization services differs significantly by site of service, we established different PHP payment rates for hospital-based PHPs and CMHCs in the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). With respect to the continued use of PHP APC geometric mean per diem costs for determining payment rates by provider, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through

[59] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR (or statewide CCR, where the overall CCR was greater than 1) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have 3 or more services provided to be assigned to CMHC APC 5853. The geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where 3 or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where 3 or more services were provided.

68412) for a discussion of the implementation of this policy. The resulting payment rates reflect the geometric mean cost of what providers expend to maintain such programs, based on data provided by CMHCs and hospital-based PHPs, which we believe is an improvement over the two-tiered methodology calculated based on median costs using only hospital-based data.

Comment: Two commenters opposed the continued use of the single-tiered payment system implemented in CY 2017 OPPS/ASC rulemaking. One of these commenters asserted that the single-tiered system was implemented due to the cost inversion in hospital-based PHP data and, therefore, was unfairly applied to CMHCs. Another commenter did not object to the single payment tier, but suggested that CMS monitor the data to ensure that the single-tiered APCs do not result in a decrease in the number of operational PHPs.

Response: We thank the commenters for their input. In the CY 2017 OPPS/ASC final rule with comment period, we cited several reasons for implementing the single-tiered payment system (81 FR 79682 through 79686), including the cost inversion in the hospital-based PHP data which the commenter cited. A cost inversion exists when, under a 2-tiered payment system, the Level 1 geometric mean per diem cost for providing exactly 3 services per day exceeds the Level 2 PHP APC geometric mean per diem cost for providing 4 or more services per day. The commenter is correct that CMHCs were not affected by a cost inversion as hospital-based PHPs were. However, in that same CY 2017 OPPS/ASC final rule with comment period, we noted that another primary reason for combining the 2-tiered system into a single tier, by provider type, was the decrease in the number of CMHCs (81 FR 79683). With a small number of providers, data from large providers with a high percentage of all PHP service days and unusually high or low geometric mean costs per day would have a more pronounced effect on the PHP APCs geometric mean per diem costs, skewing costs up or down. The effect would be magnified by continuing to split the geometric mean per diem costs further by distinguishing between Level 1 and Level 2 PHP services. A single PHP APC for each provider type for providing 3 or more PHP services per day reduces these cost fluctuations and provides more stability in the PHP APC geometric mean per diem costs.

We do not believe that the single-tier payment system will lead to a reduction in the number of PHPs because total payments to an individual CMHC using the single-tier payment system are approximately equal to total payments to that same CMHC if the previous 2-tiered payment system were used instead. The calculated rates for APCs 5853 and 5863 continue to be based upon the actual costs for CMHCs and hospital-based PHPs, respectively. Therefore, the payment rates for the single-tier PHP APCs are an appropriate approximation of provider costs, and should not result in reduced access. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), the single-tier PHP APCs are calculated by following the existing methodology for ratesetting, except that the geometric mean per diem costs for each provider type were calculated for days providing 3 or more partial hospitalization services, as opposed to being calculated separately for days with exactly 3 services and for days with 4 or more services, as was previously done. The combined PHP APCs' geometric mean costs are similar to a weighted average of actual provider costs. As such, combining the PHP APCs geometric mean per diem costs does not reduce total costs or total payments by provider type. We refer readers to the CY 2017 OPPS/ASC final rule with comment period for a detailed review of the methodology used in determining per diem costs using the single-tier PHP APCs (81 FR 79686 through 79688).

The 2017 claims data used for this CY 2019 ratesetting are the first year of data using the single-tier payment system. We will monitor the data for any unintended consequences on the number of operational PHPs associated with using the single-tier payment system. We note that the number of PHP providers is generally affected by multiple factors, such as business and market conditions, competition, estimated profit margins, private insurance coverage changes, Federal and State fraud and abuse efforts, and community support for mental health treatment.

Comment: Several commenters questioned CMS' use of the ±2 standard deviation trim on CMHC costs/per day, and asked why it was different from the OPPS ±3 standard deviation trim which is applied to hospital-based PHPs. The commenters noted that the trims were implemented to help prevent inappropriate fluctuations in the data, but were concerned that this trim removed CMHCs from the data, and that this trim resulted in the decline in the costs per day.

Response: The ±2 standard deviation trim on CMHC costs/per day was implemented in the CY 2016 OPPS final rule with comment period (80 FR 70455 through 70462) in order to protect CMHCs from having extreme costs per day inappropriately skew the CMHC PHP APC geometric mean per diem costs.

As part of the effort to increase the accuracy of the PHP per diem costs, for the CY 2016 ratesetting, we completed an extensive analysis of the claims and cost data. That analysis identified aberrant data from several providers that impacted the calculation of the proposed PHP geometric mean per diem costs. For example, we found claims with excessive CMHC charges resulting in CMHC geometric mean costs per day that were approximately the same as or more than the daily payment for inpatient psychiatric facility services. For an outpatient program like PHP, because it does not incur room and board costs such as an inpatient stay would, these costs per day were excessive. In addition, we found some CMHCs had very low costs per day (less than $25 per day) (80 FR 70456). The ±2 standard deviation trim on CMHC costs per day excludes providers with extremely low or extremely high costs per day, and protects CMHCs from having those extreme costs inappropriately skew the CMHC PHP APC geometric mean per diem costs.

In addition, in that CY 2016 OPPS final rule with comment, we noted that the ±2 standard deviation trim aligned the geometric mean and median per diem costs for the CMHC Level 2 PHP APC payment tier, which indicated that the trim removed the skewing in the data caused by the inclusion of aberrant data (80 FR 70456). We continue to believe that the ±2 standard deviation trim excludes CMHCs with aberrant data from the ratesetting process while allowing for the use of as much data as possible. In addition, we stated that implementing a ±2 standard deviation trim on CMHCs would target these aberrancies without limiting overall per diem cost increases. For normally distributed data, ±2 standard deviations from the mean capture approximately 95 percent of the data. Our analyses for the CY 2016 ratesetting also showed that a higher trim level, such as a ±2.5 standard deviation trim or the ±3 standard deviation trim used by the rest of OPPS, did not remove the CMHCs with aberrant data from the ratesetting process (80 FR 70456 and 70457).

In this CY 2019 OPPS/ASC final rule, the ±2 standard deviation trim on CMHC costs/day removed 6 CMHCs from ratesetting, which affected the final

per diem costs. It removed both low-cost and high-cost providers that fail the trim; its net effect on the CY 2019 ratesetting data was to *increase* CMHC geometric mean per diem costs. For CY 2019, if we did not apply the ±2 standard deviation trim on CMHC costs/day, the final CMHC geometric mean per diem cost would have been $120.77. This is less than the geometric mean per diem cost of $121.62 which we are finalizing, and which is after applying the ±2 standard deviation trim.

With regard to the questions about why the same trims are not used for both CMHCs and hospital-based PHPs, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70458). As we noted in that CY 2016 OPPS/ASC final rule with comment period, there are differences in the ratesetting process between hospital-based PHPs and CMHCs, which are largely due to differences between the hospital cost reports and the CMHC cost reports, and we believe that having different trims more appropriately targets aberrant data for each provider type. As noted previously, the OPPS ±3 standard deviation trim on per diem costs did not remove the aberrant CMHC data. We considered applying the ±2 standard deviation trim on per diem costs to hospital-based PHP providers, but an alternative trim on hospital-based CCRs greater than 5 allowed for use of more data from hospital-based providers and still removed aberrant data. We continue to believe this trim based on hospital-based PHP CCRs is more effective in removing aberrant hospital-based PHP data and allows for the use and retention of more data than a ±2 standard deviation trim on hospital-based PHP costs per day.

Comment: Several commenters objected to the decline in the CMHC per diem costs that were proposed, and were concerned about the ability to maintain access to services. One commenter noted that CMHCs cannot provide all of the services they provide on a daily basis at the proposed payment rate. Some commenters also stated that CMHCs incur extra costs to meet the CMHC conditions of participation (CoPs), have more costly staff, or have experienced an increase in bad debt expense. A few commenters noted that the number of CMHCs nationally had declined greatly as a result of declines in payment and payment fluctuations. One commenter stated that setting CMHCs' payment rates based on a small number of CMHCs does not reflect the actual cost of providing these services and expressed concern that basing payments at the mean or median level would result in half of CMHCs receiving payments less than their cost, which would guarantee that more CMHCs would close, further limiting access. Commenters requested that CMS reconsider the payment rate reduction, which one commenter believed resulted in PHP services moving toward extinction in the current mode. Another commenter questioned if CMS had a veiled motivation to eliminate CMHCs altogether, and wondered if CMHCs were still considered the ''fraud benefit.'' Commenters also were concerned that if CMHC access declined, beneficiaries would be pushed toward higher-cost outpatient departments, resulting in higher out-of-pocket costs for beneficiaries. One commenter noted that CMHCs are in keeping with the health care trend to service patients in their communities, rather than forcing patients to travel to a medical center.

Response: The OPPS pays for outpatient services, including partial hospitalization services, based on the geometric mean per diem costs of providing services using provider data from claims and cost reports, in accordance with statute. For this CY 2019 OPPS/ASC final rule with comment period, the final geometric mean per diem cost for CMHC APC 5853 is $121.62, which is a slight increase from the proposed geometric mean per diem cost, but a 15-percent reduction from the CY 2018 final geometric mean per diem cost.

In response to commenters concerned that CMHCs cannot provide all of the services offered on a daily basis at the proposed payment rate, we remind commenters that we calculate the PHP APC geometric mean per diem costs based on the data provided for each type of provider to determine payment for these services. The final PHP APC geometric mean per diem costs for CY 2019 reflect actual provider costs of covered services. We believe that this system provides appropriate payment for covered partial hospitalization services based on actual provider costs. We further note that section 1861(ff)(2)(I) of the Act explicitly prohibits Medicare from paying for the costs of meals or transportation, which some CMHCs incur. Therefore, these costs, although incurred by CMHCs, are not covered under the OPPS.

In response to the commenters who stated that CMHCs incur extra costs to meet the CMHC CoPs, most (if not all) of the costs associated with adhering to CoPs should be captured in the cost report data used in ratesetting and, therefore, are accounted for when computing the geometric mean per diem costs. Similar to the requirement for CMHCs to comply with CMHC CoPs, hospital-based PHPs must also comply with hospital CoPs. All Medicare-participating facilities have CoPs or other requirements that must be met, and CMHCs are not specifically being singled out for compliance, nor are there ''extra'' costs associated with the CMHC CoPs.

Allowable labor costs for providing direct patient care would also be captured in the cost report data used for ratesetting. We refer the commenters to the instructions for the CMHC cost reports for more information on capturing the costs associated with meeting CoPs and with labor costs for direct patient care, which are available online in links to Chapters 18 and 45 found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=scending*. The covered costs of providing PHP care to beneficiaries at CMHCs are captured as part of CMHC ratesetting, and include allowable labor costs and the costs of complying with CoPs.

The reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96). The reduction to bad debt reimbursement impacted all providers eligible to receive bad debt reimbursement, as discussed in the CY 2013 End-Stage Renal Disease final rule (77 FR 67518). Medicare currently reimburses bad debt for eligible providers at 65 percent. Therefore, CMHCs are not specifically being singled out for a payment reduction as a result of bad debt expenses. Because this percentage was enacted by Congress, CMS does not have the authority to change the percentage.

We appreciate the commenter's input regarding the effect any reduction in PHP payment rates would have on access to care, but we disagree with the commenter's assertion that CMS considers CMHCs to be a ''fraud benefit'' or that CMS has any motivation (veiled or otherwise) to eliminate CMHCs. Both are simply not true; we appreciate the work CMHCs do to care for a particularly vulnerable population with serious mental illnesses. We are very concerned about the decline in the number of CMHCs, but, as noted in a previous comment response in this section, we believe that a number of factors affect PHP provider closures. We will continue working to strengthen

access to both CMHCs and hospital-based PHPs for eligible Medicare beneficiaries. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers. For example, for the CY 2016 ratesetting, we extensively reviewed the methodology used for PHP ratesetting. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466), we also included a detailed description of the ratesetting process to help all PHP providers record costs correctly so that we can more fully capture PHP costs in ratesetting.

We want to ensure that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community. We agree that beneficiaries receiving care at a CMHC instead of a hospital-based PHP would have a lower out-of-pocket cost, which increases the attractiveness of CMHCs to those needing their services. We will continue to explore policy options for strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs as well as by hospital-based PHPs.

Comment: One commenter suggested that CMS consider paying CMHCs using a quality-based payment system, and that CMS use value-based purchasing. The commenter recommended that, instead of basing payment rates on estimated actual median costs of claims, CMS look at the value provided by the quality of provided services using different methods such as records reviews, denials due to lack of medical necessity or inadequate documentation, site visits, interviews with patients, and, most importantly, patient outcomes. The commenter believed that rewarding providers for higher-quality care, as measured by selected standards instead of rewarding providers by increasing costs, is a better way to improve the quality of any service.

Response: Currently, there is no statutory language explicitly authorizing a value-based purchasing program for PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS payment rates, which include PHP payment rates. Section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We also refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years. The Hospital OQR Program does not apply to CMHCs, and there are no quality measures applied to CMHCs.

Comment: One commenter noted that, in the past, CMS stated that CMHCs provide fewer services and have less costly staff than hospitals.

Response: We believe that the commenter may be referring to the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991), wherein CMS stated we believe that CMHCs have a lower cost structure than their hospital-based PHP counterparts because the data showed that CMHCs provide fewer PHP services in a day and use less costly staff than hospital-based PHPs. Those statements were based on CY 2009 claims and cost data, which differ from more recent claims and cost data. Each year, we calculate geometric mean per diem costs based on updated claims and cost reports. For example, our CY 2019 geometric mean per diem costs and the APC payment rates are based upon CY 2017 claims and cost data. We refer the commenter to the utilization data in section VIII.B.4. of this CY 2019 final rule with comment period for details on current CMHC utilization. In addition, we continually seek to increase the accuracy of our payment rates. As noted previously, as part of the effort to increase the accuracy of the PHP APCs' per diem costs, for the CY 2016 ratesetting, we completed an extensive analysis of the claims and cost data. That analysis identified aberrant data from several providers that impacted the calculation of the proposed PHP APCs' geometric mean per diem costs.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For the CY 2019 proposed rule and for this CY 2019 final rule with comment period, we followed a data preparation process for hospital-based PHP providers that is similar to that used for CMHCs by applying trims and data exclusions as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) so that our ratesetting is not skewed by providers with extreme data. Before any trimming or exclusions were applied, there were 426 hospital-based PHP providers in the final CY 2017 PHP claims data used in this CY 2019 OPPS/ASC final rule with comment period (compared to 394 hospital-based PHPs in the CY 2019 OPPS/ASC proposed rule).

For hospital-based PHP providers, we applied a trim on hospital service days when the CCR was greater than 5 at the cost center level. This trim removed hospital-based PHP service days that use a CCR greater than 5 to calculate costs for at least one of their component services. Unlike the ±2 standard deviation trim, which excluded CMHC providers that failed the trim, the CCR greater than 5 trim excluded any hospital-based PHP service day where any of the services provided on that day were associated with a CCR greater than 5 (in other words, the CCR greater than 5 trim is a (service) day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim). Applying this CCR greater than 5 trim removed from our final rule ratesetting affected service days from 3 hospital-based PHP providers with CCRs greater than 5. However, 100 percent of the service days for 1 of these affected hospital-based PHP providers had at least 1 service associated with a CCR of 9.5744, so the trim removed that 1 provider entirely from our final rule ratesetting. The two other providers remained in the ratesetting data, but with affected service days trimmed out. In addition, 48 hospital-based PHPs were removed for having no PHP costs and, therefore, no days with PHP payment. No hospital-based PHPs were removed for missing wage index data or by the OPPS ±3 standard deviation trim on costs per day.

Therefore, we trimmed out 49 hospital-based PHP providers [(1 with all service days having a CCR greater than 5) + (48 with zero daily costs and no PHP payment)], resulting in 377 (426 total − 49 excluded) hospital-based PHP providers in the data used for final rule with comment period ratesetting (compared to 374 hospital-based PHPs in the CY 2019 OPPS/ASC proposed rule). No hospital-based PHP providers were defaulted to using their overall hospital ancillary CCRs due to outlier cost center CCR values. After completing these data preparation steps, we calculated the final CY 2019 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based PHP services by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017

OPPS/ASC final rule with comment period (81 FR 79687 and 79691) to calculate the geometric mean per diem cost.[60] The final CY 2019 geometric mean per diem cost for hospital-based PHP providers that provide 3 or more services per service day (hospital-based PHP APC 5863) is $222.76 (compared to $220.52 in the CY 2019 OPPS/ASC proposed rule).

Comment: One commenter appreciated the CY 2019 per diem increase for hospital-based PHPs. The commenter stated that the minimum rate should be set at the geometric mean rate, rather than at the 2-percent reduction rate of $216.55, as providers are hit with a second 2-percent reduction again at actual claim payout. The commenter stated this reduced the hospital-based PHP rate by 4 percent total, and places more than half of the providers in a payment setting below their daily costs of providing the services.

Response: The final hospital-based PHP APC geometric mean per diem cost is $222.76, which is a slight increase from the proposed $220.52 geometric mean per diem cost in the CY 2019 OPPS/ASC proposed rule (83 FR 37131), and a 7-percent increase from the $208.09 CY 2018 final geometric mean per diem cost (82 FR 59378). In the OPPS ratesetting, the geometric mean per diem costs are the basis for the final per diem rates. However, those costs undergo additional ratesetting steps before they are developed into payment rates, a process which is described in Part 2 of the Claims Accounting narrative under supporting documentation for this CY 2019 OPPS/ASC final rule with comment period available on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. We believe that the commenter may have misunderstood that these steps are not simply a ''standard'' 2-percent reduction applied to those costs when we determine PHP APC per diem payment rates. Rather, those costs follow a ratesetting process, which can result in the final per diem payment rates being more or less than the final per diem costs due to budget neutrality and other adjustments. It is also possible that the commenter has not misunderstood the ratesetting process, but is referring to the 2 percentage point reduction in the provider's annual ratesetting update factor due to failure to comply with Hospital Outpatient Quality Reporting Program requirements, which is described in more detail in section XIII.E. of this final rule with comment period.

For the second 2-percent reduction that the commenter referenced, which the commenter noted occurs at actual claim payout, we believe that the commenter is referencing the required sequestration 2-percent reduction to the Medicare portion of claim payments. That reduction is a Congressionally-mandated decrease, established by the Budget Control Act of 2011 (Pub. L. 112–25) and amended by the American Taxpayer Relief Act of 2012 (Pub. L. 112–240). Sequestration is discussed in a Medicare Fee-for-Service Provider eNews article available at: *https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf*. The reduction in payments due to sequestration is outside the scope of the CY 2019 OPPS/ASC proposed rule and this final rule with comment period.

Regarding the usage of the geometric mean per diem cost for determining payment rates, as we noted in a previous comment response in this section, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412) for a discussion of the implementation of this policy. We believe that this system provides appropriate payment for partial hospitalization services based on actual provider costs. The final PHP APC geometric mean per diem costs for CY 2019 reflect these actual provider costs, using our existing methodology.

After consideration of the public comments we received, we are finalizing our proposals, without modification, to continue to follow our existing ratesetting methodologies for both CMHCs and for hospital-based PHPs in determining geometric mean per diem costs. Specifically, we are applying our established methodologies in developing the CY 2019 geometric mean per diem costs and payment rates, including the application of a ±2 standard deviation trim on costs per day for CMHCs and a CCR greater than 5 hospital service day trim for hospital-based PHP providers. We also are finalizing our proposals, without modification, to continue to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)) and base the CMHC geometric mean per diem costs on the most recent available CMHC claims and CMHC cost data, and the hospital-based PHP geometric mean per diem costs on the most recent available hospital claims and cost data.

The final CY 2019 PHP APC geometric mean per diem costs for CMHC PHP APC 5853 are $121.62 and for hospital-based PHP APC 5863 are $222.76, as stated above and shown in Table 43. The final PHP APCs payment rates, which are derived from these PHP APCs geometric mean per diem costs, are included in Addendum A to this final rule with comment period (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[61]

[60] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; that CCR is determined by using the OPPS Revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have 3 or more services provided to be assigned to hospital-based PHP APC 5863. The geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where 3 or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the geometric mean per diem cost for hospital-based PHP APC 5863.

[61] As discussed in section II.A. of this CY 2019 OPPS/ASC final rule with comment period, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of this final rule with comment period for more information on scaling the weights, and for details on the final steps of the process that lead to PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

TABLE 43.—CY 2019 FINAL PHP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2019 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$222.76

3. Changes to the Revenue-Code-to-Cost Center Crosswalk

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79691), we received public comments identifying an issue that may have contributed to a decreased PHP median cost for hospital-based PHPs. The commenters stated that the lack of a required standardized PHP cost center on the Medicare cost report may be creating some cost-finding nuances in the cost report itself—for example, inaccurate step-down of overhead cost allocations to the PHP program, diluted CCRs by the comingling of PHP and ''Intensive Outpatient Program (IOP)'' on the cost report, among others. We agreed with the commenters that, if PHP costs are combined with other less intensive outpatient mental health treatment costs in the same cost center, the CCR values could be diluted, leading to lower geometric mean per diem costs being calculated. We stated in response that we would consider adding a cost center to the hospital cost report for PHP costs only.

On November 17, 2017, in Transmittal No. 12, we added a new cost center, ''Partial Hospitalization Program,'' on Line 93.99 of Worksheet A (Line 93.99 is also displayed on Worksheets B, Parts I and II, B–1; and C, Parts I and II) for hospital-based PHPs, for cost reporting periods ending on or after August 31, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). On January 30, 2018, in Transmittal No. 13, we changed the implementation date from cost reporting periods ending on or after August 31, 2017, to cost reporting periods ending on or after September 30, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R12P240.pdf*). The instructions for this new PHP cost center (Line 93.99) indicate that effective for cost reporting periods ending on or after September 30, 2017, the provider is to enter the costs of providing hospital-based partial hospitalization program (PHP) services as defined in section 1861(ff) of the Act. Therefore, this cost center is to include all costs associated with providing PHP services, as defined in the statute (for example, occupational therapy, individual and group therapy, among others). It should not include costs for non-PHP outpatient mental health services, such as costs from what providers refer to as ''Intensive Outpatient Programs.''

During current hospital-based PHP ratesetting, costs are estimated by multiplying revenue code charges on the claim by the appropriate cost center-level CCR from the hospital cost report (80 FR 70465). Each PHP revenue code is associated with particular cost centers on the cost report (80 FR 70464). The appropriate cost center-level CCR is identified by using the OPPS Revenue-Code-to-Cost-Center crosswalk; the current crosswalk is discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228) and is available on the CMS website at: *https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPPS-FR-Revenue-Code-to-Cost-Center-Crosswalk.zip*. The Revenue-Code-to-Cost-Center crosswalk identifies the primary, secondary (if any), and tertiary (if any) cost centers that are associated with each PHP revenue code, and which are the source for the CCRs used in PHP ratesetting. As discussed in the CY 2002 OPPS interim final rule (66 FR 59885), hospital-based PHP CCRs are assessed by applying the existing OPPS ±3 standard deviation trim to hospital-based PHP CCRs within each cost center and to the overall hospital ancillary CCR. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464), we stated that, if the primary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will look for a CCR in the secondary cost center. If the secondary cost center has no CCR or if it fails the ±3 standard deviation trim, the system will move to the tertiary cost center to look for a CCR. If the tertiary cost center has no CCR or if it fails the ±3 standard deviation trim, the ratesetting system will default to using the hospital's overall ancillary CCR. If the hospital's overall ancillary CCR fails the ±3 standard deviation trim, we exclude the hospital from ratesetting. While the hierarchy requires a primary cost center to be associated with a given revenue code, it is optional for there to be secondary or tertiary cost centers.

With the new PHP cost center, the crosswalk must be updated for hospital-based PHP cost estimation to correctly match hospital-based PHP revenue code charges with the PHP cost center CCR for future ratesetting. However, because the PHP-allowable revenue codes are also used for reporting non-PHP mental health services, we could not designate the PHP cost center as the primary cost center in the existing OPPS Revenue-Code-to-Cost-Center crosswalk. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37132 through 37133), we proposed to create a separate PHP-only Revenue-Code-to-Cost-Center crosswalk for use in CY 2019 and subsequent years, which would provide a more accurate and operationally simpler method of matching hospital-based PHP charges to the correct hospital-based PHP cost center CCR without affecting non-PHP ratesetting. We note that, because CMHCs have their own cost reports, we use each CMHC's overall CCR in estimating costs for PHP ratesetting (80 FR 70463 through 70464). As such, CMHCs do not have a crosswalk and, therefore, the proposal to create a PHP-only crosswalk does not apply to CMHCs.

Therefore, we proposed that, for CY 2019 and subsequent years, hospital-

based PHPs would follow a new Revenue-Code-to-Cost-Center crosswalk that only applies to hospital-based PHPs. We proposed that this new PHP-only Revenue-Code-to-Cost-Center crosswalk would be comprised of the existing PHP-allowable revenue codes and would map each of those PHP-allowable revenue codes to the new PHP cost center Line 93.99 as the primary cost center source for the CCR. We also proposed to designate as the new secondary cost center the cost center that is currently listed as the existing primary cost center, and to designate as the new tertiary cost center the cost center that is listed as the existing secondary cost center.

In addition, we proposed one exception to this policy for the mapping for revenue code 0904, which is the only PHP-allowable revenue code in the existing crosswalk with a tertiary cost center source for the CCR. We proposed that for revenue code 0904, the secondary cost center for CY 2019 and subsequent years would be the existing secondary cost center 3550 (''Psychiatric/Psychological Services''). Similarly, we proposed that for revenue code 0904, the tertiary cost center for CY 2019 and subsequent years would be existing tertiary cost center 9000 (''Clinic''). We considered expanding the Revenue-Code-to-Cost-Center crosswalk hierarchy to add a 4th or quaternary level to the hierarchy, before the system would default to the overall hospital ancillary CCR. However, we evaluated the usage of the current hierarchy for revenue code 0904 for the CY 2017, CY 2018, and CY 2019 PHP ratesetting modelling, and found that expanding the hierarchy would not be necessary. Our analysis showed that the existing primary cost center 3580 (''Recreational Therapy'') for revenue code 0904 had not been used during any of the past 3 years.

We did not receive any public comments on our proposals related to the PHP-only Revenue-Code-to-Cost-Center crosswalk and, therefore, are finalizing our proposals, as proposed, for CY 2019 and subsequent years.

Our previous and newly finalized PHP-only Revenue-Code-to-Cost-Center Crosswalks are shown in Table 44 below.

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TABLE 44.—PREVIOUS AND NEWLY FINALIZED PHP-ONLY REVENUE—CODE-TO-COST-CENTER CROSSWALKS

PHP Allowable Revenue Code	Previous Hierarchy (applicable in CY 2018)			Finalized New PHP-only Hierarchy (applicable in CY 2019 and beyond)		
	Primary Cost Center Source for CCR	Secondary Cost Center Source for CCR	Tertiary Cost Center Source for CCR	Primary Cost Center Source for CCR	Secondary Cost Center Source for CCR	Tertiary Cost Center Source for CCR
0430	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0431	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0432	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0433	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0434	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0435	RESERVED					
0436	RESERVED					
0437	RESERVED					
0438	RESERVED					
0439	6700 Occupational Therapy			9399 (PHP)	6700 Occupational Therapy	
0900	3550 (Psychiatric/ Psychological Services	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)
0904	3580 (Recreational Therapy)	3550 (Psychiatric/ Psychological Services	9000 (Clinic)	9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)

PHP Allowable Revenue Code	Previous Hierarchy (applicable in CY 2018)			Finalized New PHP-only Hierarchy (applicable in CY 2019 and beyond)		
	Primary Cost Center Source for CCR	Secondary Cost Center Source for CCR	Tertiary Cost Center Source for CCR	Primary Cost Center Source for CCR	Secondary Cost Center Source for CCR	Tertiary Cost Center Source for CCR
0914	3550 (Psychiatric/ Psychological Services	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)
0915	3550 (Psychiatric/ Psychological Services	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)
0916	3550 (Psychiatric/ Psychological Services	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)
0918	3550 (Psychiatric/ Psychological Services	9000 (Clinic)		9399 (PHP)	3550 (Psychiatric/ Psychological Services)	9000 (Clinic)
0942	9000 (Clinic)			9399 (PHP)	9000 (Clinic)	

4. PHP Service Utilization Updates

We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37133 through 37134) that, while we were not proposing any changes to the policy on PHP service utilization, we would continue to monitor the provision of days with only 3 services. In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2017 claims data used for this CY 2019 final rule with comment period revealed some changes in the provision of individual therapy compared to CY 2016 and CY 2015 claims data as shown in the Table 45 below.

TABLE 45.—PROVISION OF INDIVIDUAL THERAPY, BY PROVIDER TYPE AND CLAIMS YEAR

	Percent of Days with 3 Services Only	Percent of Days with 4 or More Services
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%

As shown in Table 45, both CMHCs and hospital-based PHPs have decreased the provision of individual therapy, based on the CY 2017 claims used for this final rule with comment period.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33640 and 82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing 4 or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of APC 5853 and APC 5863 for providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For this CY 2019 OPPS/ASC final rule with comment period, we used the final update of the CY 2017 claims data. Table 46 below shows the utilization findings based on the most recent claims data.

TABLE 46.—PERCENTAGE OF PHP DAYS BY SERVICE UNIT FREQUENCY

	CY 2015	CY 2016*	CY 2017*	% Change**
CMHCs:				
Percent of Days with 3 services	4.7%	4.8%	5.6%	16.7%
Percent of Days with 4 services	62.9%	70.3%	74.0%	5.3%
Percent of Days with 5 or more services	32.4%	24.9%	20.5%	-17.7%
Hospital-based PHPs:				
Percent of Days with 3 services	12.4%	10.9%	9.8%	-10.1%
Percent of Days with 4 services	69.8%	64.9%	56.4%	-13.1%
Percent of Days with 5 or more services	17.8%	24.1%	33.9%	40.7%

*May not sum to 100 percent by provider type due to rounding.
**(CY 2017 – CY 2016) / CY 2016

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As shown in Table 46, the CY 2017 claims data used for this final rule with comment period showed that PHPs maintained an appropriately low utilization of 3 service days compared to CY 2016 and CY 2015. Compared to CY 2016, hospital-based PHPs have provided fewer days with 3 services only, fewer days with 4 services only, and more days with 5 or more services. Compared to CY 2016, CMHCs have slightly increased their provision of 3 service days, increased their provision of days with 4 services, but have decreased their provision of days with 5 or more services.

As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only 3 services, particularly now that the single-tier PHP APCs 5853 and 5863 are in place for providing 3 or more services per day to CMHCs and hospital-based PHPs, respectively. The CY 2017 data are the first year of claims data to reflect the change to the single-tier PHP APCs, and the declining level of utilization of days with 3 services only by hospital-based PHPs indicates that these providers did not reduce care for this patient population. It is too early to determine if the increase in days providing 3 services only by CMHCs is a trend. We will continue to monitor the data for both hospital-based PHPs and CMHCs.

It is important to reiterate our expectation that days with only 3 services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable *minimum* units of PHP services required in a PHP day to be 3 and explained that it was never our intention that 3 units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only 3 units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with 3 services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1), that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

We made no proposals in this section of the CY 2019 OPPS/ASC proposed rule, but received several public comments related to utilization.

Comment: Some commenters were concerned that the single-tiered payment system implemented in CY 2017 could have unintended consequences, including reducing the number of services provided per day, and urged CMS to monitor the data.

Another commenter thanked CMS for not instituting a code edit for 20 hours per week, and welcomed a further discussion of clinical intensity and situations affecting weekly attendance. This commenter offered to convene a meeting of experts from the field to discuss, develop, and recommend ideas on how best to ensure the appropriate clinical intensity in PHPs. Another commenter wrote that the utilization data in Table 28 of the CY 2019 OPPS/ASC proposed rule demonstrated the commitment of both CMHCs and hospital-based PHPs to fully comply with and exceed the expectations of the 20-hour rule.

Response: We appreciate these comments and will take them into consideration.

C. Outlier Policy for CMHCs

In the CY 2019 OPPS/ASC proposed rule (83 FR 37134 through 37136), for CY 2019, we proposed to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold according to previously established policies. These topics are discussed in more detail below. We refer readers to section II.G. of this final rule with comment period for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII. C. of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages below. As previously stated, we proposed to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2019. To calculate the CMHC outlier percentage, we followed three steps:

- Step 1: We multiplied the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

(0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.

- Step 2: We estimated CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of this final rule with comment period). That threshold was determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceeded the threshold, we multiplied that excess by 50 percent, as described in section VIII.C.3. of this final rule with comment period, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of this final rule with comment period, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we summed all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs—Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- Step 3: We determined the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1:

(Estimated CMHC Outlier Payments/Total OPPS Outlier Payments).

In CY 2018, we designated approximately 0.03 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (82 FR 59381), based on this methodology. In the proposed rule, we proposed to continue to use the same methodology for CY 2019. Therefore, based on our CY 2019 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2019, excluding outlier payments. We proposed to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3 above.

We did not receive any public comments on our proposal and, therefore, are finalizing our proposal, without modification, to continue with this existing policy on outliers, and are implementing this policy as proposed for CY 2019.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). This cutoff point is sometimes called a multiplier threshold (70 FR 68550). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR

59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

In the CY 2019 OPPS/ASC proposed rule (83 FR 37135), for CY 2019, in accordance with our existing policy, we proposed to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2019, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

We did not receive any public comments on our proposals. We are finalizing our proposals, without modification, to continue to calculate the CMHC outlier percentage according to previously established policies, and are implementing this policy as proposed for CY 2019.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. The main vulnerability in the OPPS outlier payment system is the time lag between the update of the CCRs that are based on the latest settled cost report and the current charges that creates the potential for hospitals and CMHCs to set their own charges to exploit the delay in calculating new CCRs. CMS initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37135), we proposed to continue these policies for CY 2019.

We did not receive any public comments on our proposals and, therefore, are finalizing our proposals, without modification, to continue our existing policy for CY 2019.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. For CY 2018, we continued this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37135 through 37136), we proposed to continue this policy for CY 2019, such that the CMHC outlier payment cap would be 8 percent of the CMHC's total per diem payments.

We did not receive any public comments on our proposal and, therefore, are finalizing our proposal, without modification, to continue our existing policy for CY 2019, such that the CMHC outlier payment cap will be 8 percent of the CMHC's total per diem payments.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37134 through 37136), we proposed to continue this policy for CY 2019.

We did not receive any public comments on our proposal and, therefore, are finalizing our proposal, without modification, to continue with this existing policy, and are implementing this policy as proposed for CY 2019.

D. Proposed Update to PHP Allowable HCPCS Codes

CMS received the CY 2019 CPT codes from the AMA in time for inclusion in the CY 2019 OPPS/ASC proposed rule (83 FR 37088). The new, revised, and deleted CY 2019 Category I and III CPT codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We are aware that the AMA will be deleting the following psychological and neuropsychological testing CPT codes, which affect PHPs, as of January 1, 2019:

- CPT code 96101 (Psychological testing by psychologist/physician);
- CPT code 96102 (Psychological testing by technician);
- CPT code 96103 (Psychological testing administered by computer);

- CPT code 96118 (Neuropsychological testing by psychologist/physician)
- CPT code 96119 (Neuropsychological testing by technician); and
- CPT code 96120 (Neuropsychological test administered w/computer).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37088), we proposed to delete these 6 CPT codes for the 2019 OPPS update under section III.A.4. (''Proposed Treatment of New and Revised CY 2019 Category I and III CPT Codes That Will Be Effective January 1, 2019 For Which We Are Soliciting Public Comments In This CY 2019 OPPS/ASC Proposed Rule'').

In addition, the AMA will be adding the following psychological and neuropsychological testing CPT codes to replace the deleted codes, as of January 1, 2019:

- CPT code 96130 (Psychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 93131 (Psychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96132 (Neuropsychological testing evaluation by physician/qualified health care professional; first hour);
- CPT code 96133 (Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour);
- CPT code 96136 (Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes);
- CPT code 96137 (Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes);
- CPT code 96138 (Psychological/neuropsychological testing by technician; first 30 minutes);
- CPT code 96139 (Psychological/neuropsychological testing by technician; each additional 30 minutes); and
- CPT code 96146 (Psychological/neuropsychological testing; automated result only).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37088), we also proposed to recognize and assign these 9 CPT codes under the CY 2019 OPPS in section III.A.4. (''Proposed Treatment of New and Revised CY 2019 Category I and III CPT Codes That Will Be Effective January 1, 2019 For Which We Are Soliciting Public Comments In This CY 2019 OPPS/ASC Proposed Rule'').

While these proposed changes to the above-referenced codes were included in the CY 2019 OPPS/ASC proposed rule (and are being finalized in section III.A.3. in this final rule with comment period for the CY 2019 OPPS), PHP is a part of the OPPS and PHP providers may not have been aware of those proposed changes because we did not also include the proposals in the PHP discussion presented in the proposed rule. To ensure that PHP providers are aware of the codes and have the opportunity to comment on the proposed changes, we are utilizing a practice similar to the one we use under the OPPS for new Level II HCPCS codes that become effective after the proposed rule is published. Therefore, in this final rule with comment period, we are proposing to delete the same 6 CPT codes listed above from the PHP-allowable code set for CMHC APC 5853 and hospital-based PHP APC 5863, and replace them with 9 new CPT codes as shown in Table 47 below, effective January 1, 2019. We are soliciting public comments on these proposals. We will consider the public comments we receive and seek to finalize our proposed actions in the CY 2020 OPPS/ASC final rule with comment period.

TABLE 47.—PROPOSED CHANGES TO THE ALLOWABLE CPT CODES FOR CMHC PHP APC 5853 and HOSPITAL-BASED PHP APC 5863

Existing Code	Proposed Action	Proposed Replacement(s)	Proposed APC Action
96101	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96102	Delete	96130, 96131, and may also include 96136, 96137, 96138, 96139, 96146	Add
96103	Delete	96130, 96131, and may also include 96136 96137, 96138, 96139, 96146	Add
96118	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96119	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add
96120	Delete	96132, 96133, and may also include 96136, 96137, 96138, 96139, 96146	Add

IX. Procedures That Will Be Paid Only as Inpatient Procedures

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full historical discussion of our longstanding policies on how we identify procedures that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, will not be paid by Medicare under the OPPS, and on the criteria that we use to review the IPO list each year to determine whether or not any procedures should be removed from the list. The complete list of codes that describe procedures that will be paid by Medicare in CY 2019 as inpatient only procedures is included as Addendum E to this CY 2019 OPPS/ASC final rule with comment period, which is available via the internet on the CMS website.

B. Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

In the CY 2019 OPPS/ASC proposed rule (83 FR 37136 through 37143), for CY 2019, we proposed to use the same methodology (described in the November 15, 2004 final rule with comment period (69 FR 65834)) of reviewing the current list of procedures on the IPO list to identify any procedures that may be removed from the list. We have established five criteria that are part of this methodology. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing procedures to determine whether or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.

2. The simplest procedure described by the code may be performed in most outpatient departments.

3. The procedure is related to codes that we have already removed from the IPO list.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

5. A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Using the above-listed criteria, for the CY 2019 OPPS, we identified two procedures described by the following codes that we proposed to remove from the IPO list for CY 2019: CPT code 31241 (Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery) and CPT code 01402 (Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty). We also proposed to add to the IPO list for CY 2019 the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel). Table 29 of the proposed rule (83 FR 37137) displayed the proposed changes to the IPO list for CY 2019 and subsequent years, including the HCPCS codes, long descriptors, and the proposed CY 2019 payment indicators.

As noted earlier, we proposed to remove the procedure described by CPT code 31241 from the IPO list for CY 2019. Specifically, we stated that after reviewing the clinical characteristics of the procedure described by CPT code 31241 and consulting with stakeholders and our clinical advisors regarding this procedure, we believed that this procedure met criterion 3; that is, the procedure is related to codes that we have already removed from the IPO list. We proposed that the procedure described by CPT code 31241 be assigned to C–APC 5153 (Level 3 Airway Endoscopy) with a status indicator of ''J1.'' We sought public comments on whether the public believes that the procedure described by CPT code 31241 meets criterion 3 and whether the procedure meets any of the other five criteria for removal from the IPO list.

Comment: A majority of the commenters supported the proposed removal of CPT code 31241 from the IPO list and the proposed APC assignment to APC 5153 with a status indicator of ''J1''. The commenters agreed that the procedure described by CPT code 31241 meets criterion 3 (that is, the procedure described by CPT code 31241 is related to codes that we have already removed from the IPO list).

Response: We appreciate the commenters' support.

Comment: One commenter opposed the removal of CPT code 31241. However, the commenter did not provide a rationale for its opposition.

Response: We have noted the commenter's general opposition. However, for the reasons cited in the proposed rule, we continue to believe that removal of the procedure described by CPT code 31241from the IPO list is appropriate. In addition, we received support for the removal of CPT code 31241 from the IPO list from many other stakeholders.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to remove CPT code 31241 from the IPO list and to assign the procedure to C–APC 5153 (Level 3 Airway Endoscopy) with a status indicator of ''J1''.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37136), we also proposed to remove the procedure described by CPT code 01402 from the IPO list. We reviewed the clinical characteristics of the procedure described by CPT code 01402, and proposed that this procedure be removed from the IPO list because it meets above-listed criteria 3 and 4. This procedure is typically billed with the procedure described by CPT code 27447 (Arthroplasty, knee, condyle and plateau; medial and lateral compartments with or without patella resurfacing (total knee arthroplasty)), which was removed from the IPO list for CY 2018 (82 FR 52526). This procedure is also often performed safely in the outpatient department setting. We sought public comments on whether the procedure described by CPT code 01402 meets criteria 3 and 4 and whether the procedure meets any of the other five criteria for removal from the IPO list.

Comment: Commenters supported the removal of the procedure described by CPT code 01402 from the IPO list and agreed that the procedure described by CPT code 01402 was both related to codes that were previously removed from the IPO list and is performed safely in numerous hospitals on an outpatient basis.

Response: We thank the commenters for their support.

Comment: One commenter opposed the removal of the procedure described by CPT code 01402 from the IPO list because the commenter believed that there would be potential detrimental lateral impacts on hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model, the Bundled Payments for Care Improvement (BPCI) Initiative, the Hospital Value-Based Purchasing (VBP)

Program, and the Hospital Readmissions Reduction Program (HRRP).

Response: Removal of the procedure described by CPT code 01402 does not in any way affect a provider's ability to participate in any of the initiatives the commenter mentioned. We remind readers that the removal of any procedure from the IPO list does not mandate that all cases be performed on an outpatient basis. Rather, such removal allows for Medicare payment to be made to the hospital when the procedure is performed in the hospital outpatient department setting. The decision to admit a patient is a complex medical judgment that is made by the treating physician. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79698 through 79699) in which we originally proposed to remove total knee arthroplasty (TKA) procedure codes from the IPO list and sought comments on how to modify the CJR Model and the BPCI Initiative to reflect the shift of some Medicare beneficiaries from an inpatient TKA procedure to an outpatient TKA procedure in the BPCI Initiative and the CJR Model pricing methodologies, including target price calculations and reconciliation processes. However, we invite interested parties to direct any questions about these initiatives to the CMS Center for Medicare and Medicaid Innovation.

Comment: One commenter representing a coalition of industry stakeholders recommended that CMS collect and publish data on morbidity and mortality rates for TKA performed in the outpatient setting versus in the inpatient setting. The commenter believed that collecting these data would allow CMS to evaluate the quality of services in both settings since the removal of TKA procedures from the IPO list.

Response: We note that since we removed the CPT codes related to TKA from the IPO list, TKA procedures have only been payable under the OPPS for less than one year. Accordingly, we do not believe that we have sufficient data at this time for a meaningful comparison of quality outcomes associated with TKA procedures performed in the hospital outpatient setting versus the hospital inpatient setting. However, we will consider reviewing mortality rates in the future when appropriate data are available. We would not expect there to be statistically significant differences in morbidity and mortality among Medicare beneficiaries based solely on whether the patient was admitted to the hospital or remained a hospital outpatient (especially because it is likely the same surgeon, the same clinical protocol, and the same staff at a given hospital for both inpatient and outpatient orthopaedic procedures) and would expect that other factors, such as underlying disease-state and condition of the patient, surgical complications, and ability to avoid blood clots and other potential adverse event within 90 days postsurgery. We remind readers that there are several short stay inpatient cases with a length of stay of 1 or 2 days, which is generally similar to the length of stay for outpatient cases. To be clear, there is a plethora of surgical procedures that may be performed on either an inpatient basis or an outpatient basis. However, we are not aware of differences in clinical outcomes for patients based solely on this factor. While there are some studies relating to the non-Medicare population regarding differences in outcomes, depending on whether the care setting is inpatient versus outpatient (which could include ASCs), we are not aware of any such studies since the TKA has become a payable procedure under the OPPS in 2018. In addition, we note that interested stakeholders are welcome to research these or other statistics by analyzing data that Medicare makes available. The Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Outpatient Quality Reporting (OQR) Program collect and share information regarding the quality of care in both the hospital inpatient setting and the hospital outpatient setting. Specifically, the Hospital IQR Program maintains measures that include complications and deaths during inpatient hip/knee replacement procedures. However, an analogous measure for outpatient procedures does not currently exist.

Comment: One commenter requested that CMS provide guidance and education regarding the removal of TKA procedures from the IPO list beginning in CY 2018. The commenter noted that there was confusion around the policy for hospital systems and health insurance plans, and that many hospital systems and Medicare Advantage plans were denying inpatient admissions by default and requiring Medicare patients to undergo a TKA procedure as a hospital outpatient.

Response: As previously stated in the discussion of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383), we continue to believe that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general requirement that any procedure be reasonable and necessary. We also reiterate our previous statement that the removal of any procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. Rather, we believe that as technology and clinical practice continue to evolve, beneficiaries should continue to receive care in the most appropriate setting.

While we continue to expect providers who perform an outpatient TKA procedure on Medicare beneficiaries to use comprehensive patient selection criteria to identify appropriate candidates for the procedure, we believe that the surgeons, clinical staff, and medical specialty societies representing physicians who perform outpatient TKA procedures and possess specialized clinical knowledge and experience are most suited to create such guidelines.

After consideration of the public comments we received, we are adopting, as final without modification, our proposal to remove the procedure described by CPT code 01402 from the IPO list. In accordance with the regulations at 42 CFR 419.2(b)(4), under the OPPS, this anesthesia service is packaged with the associated procedure and assigned status indicator ''N'' (Items and Services Packaged into APC Rates) for CY 2019.

In addition, in the CY 2019 OPPS/ASC proposed rule (83 FR 37136 through 37137), we proposed to add the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel) to the IPO list for CY 2019. The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (76 FR 74353). After evaluating the procedure described by HCPCS code C9606 using the criteria described above, we believe that the procedure should be added to the IPO list because this procedure is performed during acute myocardial infarction and it is similar to a procedure already on the IPO list (that is, the procedure described by CPT code 92941 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial

infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, artherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel)), which was added to the IPO list for CY 2018 (82 FR 52526). We sought public comments on whether the procedure described by HCPCS code C9606 should be added to the IPO list for CY 2019 and subsequent years.

Comment: Several commenters, largely from specialty medical societies, supported adding the procedure described by HCPCS code C9606 to the IPO list for CY 2019.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are adopting as final without modification, our proposal to add the procedure described by HCPCS code C9606 (Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel) to the IPO list for CY 2019.

2. Summary of Public Comments Received in Response to CMS' Solicitation on the Potential Removal of Procedure Described by CPT Code 0266T From the IPO List and Our Responses

CPT code 0266T describes the implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed). The procedure described by CPT code 0266T has been included on the IPO list since the procedure code became effective in CY 2011.

There are several codes that describe procedures that are similar to the procedure described by CPT code 0266T that are not on the IPO list, including: CPT code 0267T (Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)) and CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). The device that is billed with these two procedures has been granted a Category B Investigational Device Exemption (IDE) from FDA.[62] Currently, there is limited information available to determine the typical site of service and the ability for the procedure to be safely performed in the outpatient setting. At the time of development of the CY 2019 OPPS/ASC proposed rule, we did not believe that we had adequate information to determine whether the procedure described by CPT code 0266T should be removed from the IPO list. Therefore, we sought public comments on the removal of the procedure described by CPT code 0266T from the IPO list. Specifically, we sought public comments on whether the procedure described by CPT code 0266T meets any of the criteria to be removed from the IPO list as well as the appropriate APC assignment and status indicator for this code.

Comment: Numerous commenters responded to CMS' solicitation for discussion of the removal of the Barostim procedure from the IPO list. Commenters included the manufacturer and practitioners, specifically cardiologists and cardiovascular surgeons, who have performed the Barostim procedure multiple times. Commenters referenced their personal experience with the procedure described by CPT code 0266T, the advancements and safety of the procedure, and patients' experience after undergoing the procedure. These commenters argued that procedures related to CPT code 0266T are commonly being performed safely in the hospital outpatient department. The manufacturer specifically cited the CY 2019 NPRM CPT Cost Statistics Files associated with the proposed rule to show the number of related procedures that have been performed in the hospital outpatient department this year. Further, another commenter supported the assertion provided in the proposed rule that the simplest procedures described by CPT code 0266T, the procedure to implant or replace the lead or IPG, currently have separate and distinct CPT codes (0267T and 0268T) that are not included on the IPO list.

Response: We reviewed clinical characteristics of the Barostim procedure and related evidence, including input from multiple physician and cardiology specialty societies, and determined that the procedure described by CPT code 0266T is an appropriate candidate for removal from the IPO list. CPT code 0266T is similar to CPT code 0268T, which is performed in numerous hospitals on an outpatient basis (criterion 3). Furthermore, we believe that most outpatient departments are equipped to provide the described services to the Medicare population (criterion 1). Therefore, we are removing the procedure described by CPT code 0266T from the IPO list for CY 2019.

Comment: Several commenters recommended the removal of several procedures not originally proposed by CMS for removal from the IPO list for CY 2019. These recommended procedures related to other procedures that were recently removed from the IPO. In addition, several commenters recommended the removal of all orthopaedic, arthroplasty, and joint replacement procedures from the IPO list. Table 48 below contains the procedures that were explicitly requested by the commenters to be removed from the IPO list for CY 2019.

[62] Available at: *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html.*

TABLE 48.—PROCEDURES REQUESTED BY COMMENTERS TO BE REMOVED FROM THE INPATIENT ONLY LIST FOR CY 2019

CPT Code	Descriptors
00670	Anesthesia for extensive spine and spinal cord procedures (eg, spinal instrumentation or vascular procedures)
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral

Response: We appreciate the diligence that commenters continue to show in proposing changes to the IPO list. For the CY 2019 OPPS, we believe that it is appropriate to remove the procedure described by CPT code 00670 from the IPO list, as recommended by the commenters. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79695 through 79696) in which CMS removed six related codes (four spine procedure codes and two laryngoplasty codes) from the IPO list for CY 2017. We believe that the procedure described by CPT code 00670 is appropriate for removal from the IPO list because it relates to the following codes that CMS removed from the IPO list in CY 2017: CPT code 22840 (Posterior non-segmental instrumentation (*e.g.,* Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)); CPT code 22842 (Posterior segmental instrumentation (*e.g.,* pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)); CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)); and CPT code 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)). We also believe that this procedure is being performed in numerous hospitals on an outpatient basis. Accordingly, we are removing the procedure described by CPT code 00670 from the IPO list for CY 2019. Because this spine procedure code is an add-on code, in accordance with the regulations at 42 CFR 419.2(b)(18), under the OPPS, this procedure is packaged with the associated procedure and assigned status indicator ''N'' (Items and Services Packaged into APC Rates) for CY 2019.

With respect to the commenters' recommendation that we remove CPT code 63265 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical), CPT code 63266 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic), CPT code 63267 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar), and CPT code 63268 (Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral) from the IPO list, we intend to continue to review these procedures and the appropriateness of the potential removal from the IPO list for subsequent rulemaking.

In regard to the commenters' recommendation to remove all orthopaedic, arthroplasty, and joint replacement procedures from the IPO list, we do not believe that we have sufficient data to support removal of all orthopaedic, arthroplasty, and joint replacement procedures from the IPO list. However, we encourage stakeholders to submit specific procedures, along with evidence, to support their requests for removal from the IPO list.

In conclusion, the complete list of procedure codes that are placed on the IPO list for CY 2019 is included as Addendum E to this CY 2019 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

Table 49 below contains the final changes that we are making to the IPO list for CY 2019.

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TABLE 49.—CHANGES TO THE INPATIENT ONLY LIST FOR CY 2019

CY 2019 CPT Code	CY 2019 Long Descriptor	Action	CY 2019 OPPS APC Assignment	CY 2019 OPPS Status Indicator
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	Removed from IPO list	5153	J1
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	Removed from IPO list	N/A	N
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed).	Removed from IPO list	5463	J1
00670	Anesthesia for extensive spine and spinal cord procedures (eg, spinal instrumentation or vascular procedures)	Removed from the IPO	N/A	N
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Added to IPO list	N/A	C

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X. Nonrecurring Policy Changes

A. Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments

The June 2017 Report to Congress [63] by the Medicare Payment Advisory Commission (MedPAC) states that, in recent years, there has been significant growth in the number of health care facilities located apart from hospitals that are devoted primarily to emergency department services. This includes both off-campus provider-based emergency departments that are eligible for payment under the OPPS and independent freestanding emergency departments not affiliated with a hospital that are not eligible for payment under the OPPS. Since 2010, we have observed a noticeable increase in the number of hospital outpatient emergency department visits furnished under the OPPS. MedPAC and other entities have expressed concern that services may be shifting to the higher acuity and higher cost emergency department setting due to: (1) Higher payment rates for services performed in off-campus provider-based emergency departments compared to similar services provided in other settings (that is, physician offices or urgent care clinics); and (2) the exemption for services provided in an emergency department included under section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–25), whereby all items and services (emergency and nonemergency) furnished in an emergency department are excepted from the payment implications of section 603, as long as the department maintains its status as an emergency department under the regulation at 42 CFR 489.24(b).

MedPAC and other entities are concerned that these payment incentives may be a key factor contributing to the growth in the number of emergency departments located off-campus from a hospital. MedPAC recommended in its March 2017 [64] and June 2017 Reports to Congress that CMS require hospitals to append a modifier to claims for all services furnished in off-campus

[63] Available at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf.*

[64] Available at: *http://medpac.gov/docs/default-souce/reports/mar17_entirereport.pdf.*

provider-based emergency departments, so that CMS can track the growth of OPPS services provided in this setting.

In order to participate in Medicare as a hospital, the facility must meet the statutory definition of a hospital at section 1861(e) of the Act, which requires a facility to be primarily engaged in providing care and services to inpatients. In addition, 42 CFR 482.55 requires hospital emergency department services (to include off-campus provider-based emergency departments) to be fully integrated with departments and services of the hospital. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and furnish appropriate care for an emergency patient. Such services would include, but are not limited to, surgical services, laboratory services, and radiology services, among others. The emergency department must also be integrated with inpatient services, which means the hospital must have a sufficient number of inpatient beds and nursing units to support the volume of emergency department patients that could require inpatient services. The provision of services, equipment, personnel and resources of other hospital departments and services to emergency department patients must be within timeframes that protect the health and safety of patients and is within acceptable standards of practice.

We agree with MedPAC's recommendation and believe we need to develop data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments. Therefore, we announced in the CY 2019 OPPS/ASC proposed rule (83 FR 37138) that we are implementing through the subregulatory HCPCS modifier process a new modifier for this purpose, effective beginning January 1, 2019.

We stated in the proposed rule that we will create a HCPCS modifier (''ER''—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department. We specified in the proposed rule that the modifier would be reported on the UB–04 form (CMS Form 1450) for hospital outpatient services. We stated that critical access hospitals (CAHs) would not be required to report this modifier.

In response to our announcement of the creation of HCPCS modifier ''ER'' (Items and services furnished by a provider-based off-campus emergency department), we received the following feedback from commenters in response to the CY 2019 OPPS/ASC proposed rule: Some commenters, including MedPAC, supported the creation of HCPCS modifier ''ER'', citing the opportunity to facilitate the collection of data on services furnished in off-campus emergency departments. Other commenters were opposed to the creation of the HCPCS modifier ''ER'' because they believed it would be an undue and unnecessary administrative burden on hospitals. Another commenter expressed a desire to have a better understanding of the reasoning for the creation of the modifier.

While we note that the creation of the HCPCS modifier ''ER'' was included in the CY 2019 OPPS/ASC proposed rule as an announcement, as opposed to a proposal, and therefore was not subject to public comment, we nonetheless appreciate the feedback provided by interested stakeholders, and will consider such feedback in potential future policy development.

B. Method To Control for Unnecessary Increases in the Volume of Outpatient Services

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), when the Medicare program was first implemented, payment for hospital services (inpatient and outpatient) was based on hospital-specific reasonable costs attributable to furnishing services to Medicare beneficiaries. Although payment for most Medicare hospital inpatient services became subject to a prospective payment system (PPS) under section 1886(d) of the Act in 1983, Medicare hospital outpatient services continued to be paid based on hospital-specific costs. This methodology for payment provided little incentive for hospitals to furnish such outpatient services efficiently and in a cost effective manner. At the same time, advances in medical technology and changes in practice patterns were bringing about a shift in the site of medical care from the hospital inpatient setting to the hospital outpatient setting.

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) (Pub. L. 99–509), the Congress paved the way for development of a PPS for hospital outpatient services. Section 9343(g) of OBRA 1986 mandated that fiscal intermediaries require hospitals to report claims for services under the Healthcare Common Procedure Coding System (HCPCS). Section 9343(c) of OBRA 1986 extended the prohibition against unbundling of hospital services under section 1862(a)(14) of the Act to include outpatient services as well as inpatient services. The codes under the HCPCS enabled us to determine which specific procedures and services were billed, while the extension of the prohibition against unbundling ensured that all nonphysician services provided to hospital outpatients were reported on hospital bills and captured in the hospital outpatient data that were used to develop an outpatient PPS.

The brisk increase in hospital outpatient services further led to an interest in creating payment incentives to promote more efficient delivery of hospital outpatient services through a Medicare outpatient PPS. Section 9343(f) of OBRA 1986 and section 4151(b)(2) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) (Pub. L. 101–508) required that we develop a proposal to replace the existing hospital outpatient payment system with a PPS and submit a report to the Congress on a new proposed system. The statutory framework for the Outpatient Prospective Payment System (OPPS) was established by section 4523 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33), which amended section 1833 of the Act by adding subsection (t), which establishes a PPS for hospital outpatient department services, and by section 201 of the Balanced Budget Reconciliation Act (BBRA) of 1999 (Pub. L. 106–113), which amended section 1833(t) of the Act to require outlier and transitional pass-through payments. At the outset of the OPPS, there was significant concern over observed increases in the volume of outpatient services and corresponding rapidly growing beneficiary coinsurance. Accordingly, most of the focus was on finding ways to address those issues.

When section 4523 of the BBA of 1997 established the OPPS, it included specific authority under section 1833(t)(2)(F) of the Act that requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services.[65] In the initial rule that proposed to implement the OPPS (63 FR 47585 through 47587), we discussed several possible approaches for controlling the volume of covered outpatient department services furnished in subsequent years, solicited comments on those options, and stated that the agency would propose an appropriate ''volume control'' mechanism for services furnished in CY 2001 and beyond after completing further analysis. For the CY

[65] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

2000 OPPS, we proposed to implement a method that was similar to the one used under the Medicare Physician Fee Schedule (PFS) (known as the sustainable growth rate or ''SGR''), which would be triggered when expenditure targets, based on such factors as volume, intensity, and beneficiary enrollment, were exceeded (63 FR 47586 through 47587). However, as we discussed in the CY 2001 OPPS final rule (65 FR 18503) and the CY 2002 OPPS final rule (66 FR 59908), we delayed the implementation of the proposed volume control method as suggested by the ''President's Plan to Modernize and Strengthen Medicare for the 21st Century'' to give hospitals time to adjust to the OPPS and CMS time to continue to examine methods to control unnecessary increases in the volume of covered OPD services.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66612), we noted that we had significant concerns about the growth in program expenditures for hospital outpatient services, and that while the OPPS was developed in order to address some of those concerns, its implementation had not generally slowed that growth in expenditures. To address some of those concerns, we established a set of packaging policies beginning in CY 2008 that would explicitly encourage efficiency in the provision of services in the hospital outpatient setting and potentially control future growth in the volume of OPPS services (72 FR 66612). Specifically, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), we adopted a policy to package seven categories of items and services into the payment for the primary diagnostic or therapeutic modality to which we believe these items are typically ancillary or supportive.

Similarly, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925 through 74948), we expanded our packaging policies to include more categories of packaged items and services as part of a broader initiative to make the OPPS more like a prospective payment system and less like a per service fee schedule. Packaging can encourage hospitals to furnish services efficiently while also enabling hospitals to manage their resources with the maximum flexibility, thereby encouraging long-term cost containment, which is an essential component of a prospective payment system. While most of the packaging policies established in the CY 2014 OPPS focused on ancillary services that were part of a primary procedure, we also introduced the concept of comprehensive APCs (C–APCs) (78 FR 74861 through 74910), which were implemented beginning in the CY 2015 OPPS (79 FR 66798 through 66810). Comprehensive APCs package payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level.

While we have developed many payment policies with these goals in mind, growth in program expenditures for hospital outpatient services paid under the OPPS continues. As illustrated in Table 30 in the CY 2019 OPPS/ASC proposed rule (83 FR 37139), total spending has been growing at a rate of roughly 8 percent per year under the OPPS, and total spending under the OPPS is projected to further increase by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion. This is approximately twice the total estimated spending in CY 2008, a decade ago. We continue to be concerned with this rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth. What was once a cost-based system was mandated by law to become a prospective payment system, which arguably should have slowed the increases in program spending. To the contrary, the OPPS has been the fastest growing sector of Medicare payments out of all payment systems under Medicare Parts A and B. Furthermore, we are concerned that the rate of growth suggests that payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Therefore, to the extent that there are lower-cost sites-of-service available, we believe that beneficiaries and the physicians treating them should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons. For example, to provide for easier comparisons between hospital outpatient departments and ASCs, as previously discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), we stated in the CY 2019 OPPS/ASC proposed rule that we also will make available a website that provides comparison information between the OPPS and ASC payment and copayment rates, as required under section 4011 of the 21st Century Cures Act (Pub. L. 114–255). Making this information available can help beneficiaries and their physicians determine the cost and appropriateness of receiving care at different sites-of-service. Although resources such as this website will help beneficiaries and physicians select a site-of-service, we do not believe this information alone is enough to control unnecessary volume increases. The growth in OPPS expenditures and the increase in the volume and intensity of hospital outpatient services were illustrated in Tables 30 and 31, respectively, of the CY 2019 OPPS/ASC proposed rule (83 FR 37139 through 37140). These tables, which include updated information, are presented below.

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TABLE 50.—GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019* (in millions)

Calendar Year (CY)	Incurred Cost	Percent Increase
CY 2010	$36,774	-
CY 2011	$39,781	8.2%
CY 2012	$43,154	8.5%
CY 2013	$46,462	7.7%
CY 2014	$52,429	12.8%
CY 2015	$56,275	7.3%
CY 2016	$59,869	6.4%
CY 2017	$64,050	7.0%
CY 2018	$68,264	6.6%
CY 2019 (Estimated)	$74,468	9.1%

*Includes Medicare Part B Drug Expenditures.

TABLE 51.—PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES*

Calendar Year (CY)	Percentage Increase
CY 2011	3.7%
CY 2012	5.1%
CY 2013	5.5%
CY 2014	8.1%
CY 2015	3.4%
CY 2016	6.4%
CY 2017	5.4%
CY 2018	6.4%
CY 2019 (Estimated)	5.4%

*Includes Medicare Part B Drug Expenditures.

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As noted in its March 2018 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) found that, from 2011 through 2016, combined program spending and beneficiary cost-sharing on services covered under the OPPS increased by 51 percent, from $39.8 billion to $60.0 billion, an average of 8.6 percent per year.[66] In its 2018 report, MedPAC also noted that ''A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs''. [67] We consider these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting.

As noted in MedPAC's March 2017 Report to Congress, ''from 2014 to 2015, the use of outpatient services increased by 2.2 percent per Medicare FFS beneficiary. Over the decade ending in 2015, volume per beneficiary grew by 47 percent. One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services. This growth in part reflects hospitals purchasing freestanding physician practices and converting the billing from the Physician Fee Schedule to higher paying hospital outpatient department (HOPD) visits. These conversions shift market share from freestanding physician offices to HOPDs. From 2012 to 2015, hospital-based E&M visits per beneficiary grew by 22 percent, compared with a 1-percent decline in physician office-based visits.'' [68]

MedPAC has documented how the billing for these services has shifted from physician offices to higher-cost outpatient sites of care for several years. At the same time, MedPAC has repeated its recommendation that the difference in payment rates between hospital outpatient departments and physician offices should be reduced or eliminated. It specifically recommended in its 2012

[66] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

[67] Ibid.

[68] Available at: *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch3.pdf?sfvrsn=0.*

Report to Congress that the payment rates for E&M visits provided in hospital outpatient departments be reduced so that total payment rates for these visits are the same, whether the service is provided in a hospital outpatient department or a physician office. In its 2014 Report to Congress, MedPAC recommended that Congress direct the Secretary to reduce or eliminate differences in payment rates between hospital outpatient departments and physician offices for selected APCs. Both of these recommendations were reiterated in MedPAC's March 2017 Report to Congress.

As previously noted, in addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we also are concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in freestanding physician offices. For example, MedPAC estimates that ''the Medicare program spent $1.0 billion more in 2009, $1.3 billion more in 2014, and $1.6 billion more in 2015 than it would have if payment rates for E&M office visits in HOPDs were the same as freestanding office rates. Relatedly, beneficiaries' cost-sharing was $260 million higher in 2009, $325 million higher in 2014, and $400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings.'' [69] We believe that this volume growth and the resulting increase in beneficiary cost-sharing is unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity. If there was not a difference in payment rates, we believe that we would not have seen the increase in beneficiaries' cost-sharing and the shift in site-of-service.

In the CY 2015 OPPS/ASC proposed rule (79 FR 41013), we stated that we continued to seek a better understanding of how the growing trend toward hospital acquisition of physicians' offices and subsequent treatment of those locations as off-campus provider-based departments (PBDs) of hospitals affects payments under the PFS and the OPPS, as well as beneficiary cost-sharing obligations. We noted that MedPAC continued to question the appropriateness of increased Medicare payment and beneficiary cost-sharing when physicians' offices become hospital outpatient departments and that MedPAC recommended that Medicare pay selected hospital outpatient services at PFS rates (MedPAC March 2012 and June 2013 Reports to Congress).

To understand how this trend was affecting Medicare, we explained that we needed information on the extent to which this shift was occurring. To that end, during the CY 2014 OPPS/ASC rulemaking cycle, we sought public comment regarding the best method for collecting information and data that would allow us to analyze the frequency, type, and payment for physicians' services and hospital outpatient services furnished in off-campus PBDs of hospitals (78 FR 75061 through 75062 and 78 FR 74427 through 74428). Based on our analysis of the public comments we received, we believed that the most efficient and equitable means of gathering this important information across two different payment systems would be to create a HCPCS modifier to be reported with every code for physicians' services and hospital outpatient services furnished in an off-campus PBD of a hospital on both the CMS–1500 claim form for physicians' services and the UB–04 form (CMS Form 1450 and OMB Control Number 0938–0997) for hospital outpatient services. We noted that a main provider may treat an off-campus facility as provider-based if certain requirements at 42 CFR 413.65 are satisfied, and we define a ''campus'' at 42 CFR 413.65(a)(2) to be the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

In 2015, the Congress took steps to address the higher Medicare payments for services furnished by certain off-campus PBDs that may be associated with hospital acquisition of physicians' offices through section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015. In the CY 2017 OPPS/ASC proposed rule, we discussed section 603 of the Bipartisan Budget Act of 2015, which amended section 1833(t) of the Act. For the full discussion of our initial implementation of this provision, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729).

Section 603 of the Bipartisan Budget Act of 2015 (Section 603) amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We note that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65.

Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section. Section 603 also added a new paragraph (21) to section 1833(t) of the Act, which defines the terms ''applicable items and services'' and ''off-campus outpatient department of a provider,'' requires the Secretary to make payments for such applicable items and services furnished by an off-campus PBD under an applicable payment system (other than the OPPS), provides that hospitals shall report on information as needed for implementation of the provision, and establishes a limitation on administrative and judicial review of the Secretary's determinations of applicable items and services, applicable payment system, whether a department meets the definition of an off-campus outpatient department of a provider, and information hospitals are required to report. In defining the term ''off-campus outpatient department of a provider,'' section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Pub. L. 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility. Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of ''off-campus outpatient department of a provider,'' for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD services furnished prior

[69] Ibid.

to the date of enactment of the Bipartisan Budget Act of 2015, that is, November 2, 2015. We note that the definition of ''applicable items and services'' specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b) and the definition of ''off-campus outpatient department of a provider'' does not include PBDs located on the campus of a hospital or within the distance (described in the definition of campus at § 413.65(a)(2)) from a remote location of a hospital facility; the items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 continued to be paid under the OPPS.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79720), we established a number of policies to implement section 603 of the Bipartisan Budget Act of 2015. Broadly, we: (1) Defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

As part of developing policies to implement the section 603 amendments to section 1833(t) of the Act, we solicited public comments on information collection requirements for implementing this provision in accordance with section 1833(t)(21)(D) of the Act (81 FR 45686; 81 FR 79709 through 79710). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier ''PN'' to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS rates for nonexcepted items and services.

While the changes required by the section 603 amendments to section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service, which results in higher costs for the Medicare program, its beneficiaries, and taxpayers more generally. These differences in payment rates have unnecessarily shifted services away from the lower paying physician's office to the higher paying hospital outpatient department. We believe that the higher payment that is made under the OPPS, as compared to payment under the PFS, contributes to incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting. In 2012, Medicare was paying approximately 80 percent more for a 15-minute office visit in a hospital outpatient department than in a freestanding physician office.[70]

For example, under Medicare payment policy in effect for CY 2018, the Medicare program would pay more for a clinic visit (HCPCS code G0463) furnished under the OPPS than it would for the visit codes under the PFS. In the CY 2017 OPPS/ASC interim final rule, we noted that the most frequently billed service with the ''PO'' modifier was described by HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is paid under APC 5012 (Clinic Visits and Related Services); the total number of CY 2017 claim lines for this service was approximately 10.8 million lines with the ''PO'' modifier as of October 2018, out of a total 30.5 million lines in CY 2017. When services are furnished in the hospital outpatient setting, an additional payment for the professional services is generally made under the PFS using the ''facility'' rate. For example, in CY 2017, the OPPS payment rate for APC 5012, which is the APC to which the outpatient clinic visit code was assigned, was $106.56. The CY 2017 PFS ''facility'' payment rate for a Level 3 visit, a service that commonly corresponds to the OPPS clinic visit, was $77.88 for a new patient and $51.68 for an established patient.

However, when services are furnished in the physician office setting, only one payment is made—typically, the ''nonfacility'' rate under the PFS. The CY 2017 PFS nonfacility payment rates for a Level 3 visit, a commonly billed service under the PFS, was $109.46 for a new patient and $73.93 for an established patient. Therefore, the total Medicare Part B payment rate (for the hospital and professional service) for a new patient when the service was furnished in the hospital outpatient setting was $184.44 ($106.56 + $77.88) compared to $109.46 in the physician office setting (approximately $75 or 68 percent more per visit), or for an established patient, $158.24 ($106.56 + $51.68) in the hospital outpatient setting compared to $73.93 in the physician office setting (approximately $84 or 114 percent more per visit). Under these examples, the payment rate was approximately $75 to $84 more for the same service when furnished in the hospital outpatient setting instead of the physician office setting, 20 percent of which was the responsibility of the beneficiary. Taking into account that this payment discrepancy occurs across tens of millions of claims each year, this is a significant source of unnecessary spending by Medicare beneficiaries directly (in the form of unnecessarily high copayments) and on behalf of Medicare beneficiaries (in the form of unnecessarily high Medicare payments for services that could be performed in a different setting).

We understand that many off-campus departments converted from physicians' offices to hospital outpatient departments without a change in either the physical location or a change in the acuity of the patients seen. To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe the difference in payment for these services is a significant factor in the shift in services from the physician's office to the hospital outpatient department, thus unnecessarily increasing hospital outpatient department volume and Medicare program and beneficiary expenditures.

We consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the

[70] Available at: *http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf.*

higher paid setting due to payment incentives. We believe the increase in the volume of clinic visits is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could likely be safely provided in a lower cost setting, we believe that the growth in clinic visits paid under the OPPS is unnecessary. Further, we believe that capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method of capping payment will control unnecessary volume increases both in terms of numbers of covered outpatient department services furnished and costs of those services.

Therefore, given the unnecessary increases in the volume of clinic visits in hospital outpatient departments, in the CY 2019 OPPS/ASC proposed rule (83 FR 37142), for the CY 2019 OPPS, we proposed to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines). Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier ''PN'') already receive a PFS-equivalent payment rate for the clinic visit.

In CY 2019, for an individual Medicare beneficiary, the standard unadjusted Medicare OPPS proposed payment for the clinic visit was approximately $116, with approximately $23 being the average copayment. The proposed PFS equivalent rate for Medicare payment for a clinic visit was approximately $46, and the copayment would be approximately $9. Under this proposal, an excepted off-campus PBD would continue to bill HCPCS code G0463 with the ''PO'' modifier in CY 2019, but the payment rate for services described by HCPCS code G0463 when billed with modifier ''PO'' would now be equivalent to the payment rate for services described by HCPCS code G0463 when billed with modifier ''PN''. This would save beneficiaries an average of $14 per visit. For a discussion of the amount paid under the PFS for clinic visits furnished by nonexcepted off-campus PBDs, we referred readers to the CY 2018 PFS final rule (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule and final rule.

In addition, in the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we proposed to implement this proposed method in a nonbudget neutral manner. Specifically, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, we note that this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled ''Periodic review,'' provides, in part, that the Secretary must annually review and revise the groups, the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors'' (emphasis added). Section 1833(t)(9)(B) of the Act, titled ''Budget neutrality adjustment'' provides that if ''the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made'' (emphasis added). However, section 1833(t)(2)(F) of the Act is not an ''adjustment'' under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent year.* We interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method.

We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS final rule with comment period (72 FR 66613). This estimated payment impact was displayed in Column 5 of Table 42.— Estimated Impact of the Proposed Changes for the Hospital Outpatient Prospective Payment System in the CY 2019 OPPS/ASC proposed rule (83 FR 37228 through 37229). An estimate that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's Budget approximates the estimated savings at $760 million, with $610 million of the savings accruing to Medicare, and $150 million saved by Medicare beneficiaries in the form of reduced copayments. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a nonbudget neutral manner. The impact associated with this proposal is further described in section XXI. of the CY 2019 OPPS/ASC proposed rule.

Comment: Numerous commenters, including organizations representing private health insurance plans, physician associations, specialty medical associations, and individual Medicare beneficiaries, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed will help to control costs for both beneficiaries and the Medicare program, as well as foster greater competition in the physician services market. Commenters were

supportive of the immediate impact this policy would have in lowering Medicare beneficiaries' out-of-pocket costs. One commenter noted that there ''is no principled basis for treating excepted and nonexcepted PBDs differently with respect to payment for E&M services or for perpetuating the payment differential between off-campus PBDs and physician offices.'' Several commenters supported implementing this policy in a nonbudget neutral manner because they believed to do otherwise would be simply to redistribute expenditures for unnecessary services within the OPPS rather than eliminating those expenditures from the OPPS altogether. A number of commenters urged CMS to continue on a path to bring full parity in payment for outpatient services, regardless of the site-of-service, to lower beneficiary cost-sharing, reduce Medicare expenditures, and stem the tide of provider consolidation. Two commenters believed that several factors demonstrate to them that HOPDs drive up volume for several other common outpatient services, including:

- Patients receive more chemotherapy administration sessions, on average, when treated in the HOPD. Chemotherapy days per beneficiary were an estimated 9 to 12 percent higher in the hospital outpatient department than the physician office setting.[71]

- Differences in utilization of chemotherapy drugs and services between hospital outpatient departments and physicians' offices resulted in an estimated increase in Medicare payments and Medicare beneficiary copayments of $167 million. Over 93 percent of the additional payments were related to chemotherapy and other chemotherapy-related drugs.[72]

- Cardiac imaging procedures resulted in higher payments for a 3-day episode (217 percent) and 22-day episodes (80 percent) when performed in a HOPD compared to a physician's office.[73]

- For certain cardiology, orthopedic, and gastroenterology services, employed physicians were seven times more likely to perform services in a HOPD setting than independent physicians, resulting in additional costs of $2.7 billion to Medicare and $411 million in patient copayments over a 3-year period.[74]

One commenter believed that payment differentials between independent physician practices and hospital outpatient departments stem in part from inadequate Medicare physician payment rates and that any savings from site neutrality proposals derived from OPPS should be reinvested in increasing payment rates elsewhere in Part B, including payments to physicians. Some commenters urged HHS to work with Congress to expand site-neutral policies in the OPPS.

Response: We appreciate the commenters' support. As mentioned in the proposed rule (83 FR 37138 through 37143), we share the commenters' concern that the current payment incentives, rather than patient acuity or medical necessity, are affecting site-of-service decision-making. As we noted in the proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs''.[75] We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices.

We appreciate the comments supporting the implementation of this policy in a nonbudget neutral manner. As we stated in the proposed rule (83 FR 37138 through 37143), we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume of services within the OPPS system in the aggregate. As detailed later in this section, we are finalizing our proposal, with modifications, in response to public comments. We will continue to take information submitted by the commenters into consideration for future study.

With respect to the comment that it is inappropriate to establish a PFS-equivalent rate because PFS rates are inadequate and that any savings should be redistributed across Medicare Part B, we disagree that PFS rates as a whole are inadequate and note that the methodology to develop such rates was established by law and regulations and is updated each year through notice-and-comment rulemaking. We note that the overall amount of Medicare payments to physicians and other entities made under the PFS is determined by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent the commenter believes that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage the commenter to nominate the service for review as a potentially misvalued service under the PFS.

Comment: MedPAC supported the proposal to reduce the OPPS payment rate for clinic visits provided in an excepted off-campus PBD to a PFS-equivalent payment rate. MedPAC noted that the policy would be consistent with its past recommendations for site-neutral payments between HOPDs and freestanding physician offices. In its comments, MedPAC highlighted two key points from its March 2012 recommendation on site-neutral payments. While MedPAC recommended that OPPS payment rates for clinic visits be reduced so that Medicare payments for these services are the same whether they are provided in HOPDs or physician offices, it also recommended that this policy be phased in over 3 years to allow providers time to adjust to lower payment rates. During the phase-in, MedPAC recommended that payment reductions to hospitals with a disproportionate share (DSH) patient percentage at or above the median be limited to 2 percent of overall Medicare payments because these hospitals are often the primary source of care for low-income beneficiaries and limiting the reduction in revenue would help maintain access to care for these beneficiaries.

Response: We thank MedPAC for its comments and support of this policy. In its comments, MedPAC recommended this policy be phased in over 3 years to allow providers time to adjust to lower payment rates. As detailed later in this section, we will be implementing this policy with a 2-year phase-in. We believe that a 2-year phase-in allows us

[71] The Moran Company: Cost Differences in Cancer Care Across Settings; August 2013.

[72] BRG: Impact of Medicare Payments of Shift in Site of Care for Chemotherapy Administration; June 2014.

[73] Avalere: Medicare Payment Differentials Across Outpatient Settings of Care; February 2016.

[74] Avalere, PAI: Physician Practice Acquisition Study: National and Regional Employment Changes, October 2016.

[75] Available at: *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0.*

to balance the immediate need to address the unnecessary increases in the volume of clinic visits with concerns like those articulated by MedPAC regarding providers' need for time to adjust to these payment changes. While we acknowledge and share MedPAC's concern about beneficiary access to care, we do not believe that a limit on the payment reduction to hospitals with a DSH patient percentage at or above the median is necessary because we believe the increase in the volume of clinic visits in excepted off-campus provider-based departments of hospitals with high DSH percentages is equally unnecessary as it is at other hospitals.

Many commenters challenged the statutory authority for various aspects of the proposal. These comments are summarized below.

Comment: Several commenters disagreed with CMS' interpretation of section 1833(t)(2)(F) of the Act. The commenters contended that section 1833(t)(2)(F) of the Act does not confer direct authority on CMS to modify OPPS payment rates for specific services. Rather, the commenters asserted that section 1833(t)(2)(F) of the Act only permits the agency to develop a ''method,'' which the commenters interpreted to mean a ''way of doing things'' or a ''plan.'' The commenters stated that utilizing the authority at section 1833(t)(2)(F) of the Act to reduce payments to excepted off-campus PBDs to rates that equal the lower payment amounts received by nonexcepted off-campus PBDs was improper. The commenters maintained that the Secretary can only control unnecessary increases in volume using authority conferred by other provisions of section 1833(t) of the Act, such as through the equitable adjustment authority at section 1833(t)(2)(E) of the Act. The commenters believed that the clinic visit proposal was arbitrary and capricious for this and other reasons. In particular, the commenters expressed concern that there was no data-driven basis to conclude that OPD services have increased unnecessarily. The commenters also claimed that the proposal is based on unsupported assertions and assumptions regarding increases in volume. The commenters were concerned that other factors, such as the shift from inpatient services to outpatient services or the 2-midnight policy, might be driving the increases in the volume of outpatient services. Other commenters asserted that CMS should consider the impact of severity of illness and patient demographics on outpatient volume prior to moving forward with any payment changes. One commenter stated that, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and EDs;
- Are more likely to live in low-income areas;
- Are 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.4 times more likely to be nonwhite;
- Are 1.6 times more likely to be under age 65 and disabled; and
- Are 1.1 times more likely to be over 85 years old.

The commenters also noted that Medicare beneficiaries with cancer seen in HOPDs relative to those beneficiaries seen in physician offices have more severe chronic conditions, higher prior utilization of services in hospitals and emergency departments, and higher likelihood of residing in low-income areas. In addition, the commenters noted that these cancer patients were more likely to be dually eligible for Medicare and Medicaid and be nonwhite, under age 65, and disabled.

Response: After consideration of these comments, we continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary broad authority to develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[76] We continue to believe shifts in the sites of service described in the preceding paragraphs are inherently unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to the payment incentives created by the difference in payment amounts. While we did receive some data illustrating that HOPDs serve unique patient populations and provide services to medically complex beneficiaries, these data did not demonstrate the need for higher payment for all clinic visits provided in HOPDs. The fact that the commenters did not supply data supporting these assertions is suggestive that the payment differential may be the main driver for unnecessary volume increases in outpatient department services, particularly clinic visits.

In fact, the Government Accountability Office (GAO) found that ''the percentage of E/M visits—as well as the number of E/M office visits per beneficiary—performed in HOPDs, rather than physician offices, was generally higher in counties with higher levels of vertical consolidation in 2007–2013.'' [77] Vertical consolidation is the practice of hospitals acquiring physician practices. We believe that higher payment rates for services furnished in HOPDs, which include clinic visits, have led hospitals to increasingly purchase physician practices. We believe there is a correlation among the increasing volume of HOPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. The GAO discovered that ''the median percentage of E/M office visits performed in HOPDs in counties with the lowest levels of vertical consolidation was 4.1 percent in 2013. In contrast, this rate was 14.1 percent for counties with the highest levels of consolidation.'' The GAO also found that, in 2013, the number of E/M office visits performed in HOPDs per 100 beneficiaries was 26 for the counties with low levels of vertical consolidation, whereas the number was substantially higher—82 services per 100 beneficiaries—in counties with the highest levels of vertical consolidation.[78] The GAO determined that the association between higher levels of vertical consolidation and high utilization of E/M office visits in HOPDs remained even after controlling for differences in county-level characteristics and other market factors that could affect the setting in which E/M office visits are performed. The GAO describes the model it ran as a ''regression model that controlled for county characteristics that do not change over relatively short periods of time, such as whether a county is urban or rural, and county characteristics that could change over time, such as the level of competition among hospitals and physicians within counties.'' The GAO explained that its ''regression model's results were similar to [its] initial results: the level of vertical consolidation in a county was significantly and positively associated with a higher number and percentage of E/M office visits performed in HOPDs—that is, as vertical consolidation increased in a given county, the number and percentage of E/M office visits

[76] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

[77] Available at: *https://www.gao.gov/assets/680/674347.pdf.*

[78] Ibid.

performed in HOPDs in that county also tended to be higher.'' [79]

The GAO findings align with our assertions in the proposed rule (83 FR 37138 through 37143). Paying substantially more for the same service when performed in an HOPD rather than a physician office provides an incentive to shift services that were once performed in physician offices to HOPDs after consolidation has occurred. The GAO findings suggest that providers responded to this financial incentive: E/M office visits were more frequently performed in HOPDs in counties with higher levels of vertical consolidation. The GAO found this association in both of its analyses of E/M office visit utilization in counties with varying levels of vertical consolidation and in its regression analyses.

We heard from many commenters that the higher payment rate was justified by the fact that HOPDs were treating sicker patient populations. The GAO's study did not support this conclusion. It examined counties that experienced large growth in the billing of clinic visits in HOPDs and was able to determine that: ''Beneficiaries from counties with higher levels of vertical consolidation were not sicker, on average, than beneficiaries from counties with lower levels of consolidation. Specifically, beneficiaries from counties with higher levels of vertical consolidation tended to have either similar or slightly lower median risk scores, death rates, rates of end-stage renal disease, and rates of disability compared to those from counties with lower levels of consolidation. Further, counties with higher levels of consolidation had a lower percentage of beneficiaries dually eligible for Medicaid, who tend to be sicker and have higher Medicare spending than Medicare beneficiaries who are not dually eligible for Medicaid.''

This suggests that areas with higher E/M office visit utilization in HOPDs are not composed of sicker-than-average beneficiaries. As we stated in the proposed rule (83 FR 37138 through 37143), paying more for the same service when performed in an HOPD rather than a physician's office provides an incentive to shift services that were once performed in physician offices to HOPDs. The GAO's findings suggest that providers responded to this financial incentive. As we noted in the proposed rule (83 FR 37138 through 37143), we have developed many payment policies, such as packaging policies and comprehensive APCs, to address the rapid growth of services in the OPPS. However, these policies have not been able to control for unnecessary increases in volume that are due to site-of-service payment differentials, which create an incentive to furnish a service in the OPD that could be furnished in a lower cost setting based solely on the higher payment amount available under the OPPS. Here, the clinic visit service furnished in excepted off-campus PBDs is the same as the clinic visit service furnished in nonexcepted off-campus PBDs. We believe that applying an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act is an appropriate method to control the unnecessary increase in the volume of outpatient services.

Comment: Several commenters expressed concern that CMS lacks the statutory authority to reduce OPPS payments for certain clinic visit services furnished at off-campus PBDs that are excepted from payment ''under the applicable payment system'' under section 1833(t)(21) of the Act. The commenters stated that Congress expressly chose in section 603 of the Bipartisan Budget Act of 2015 not to confer on CMS authority to pay excepted off-campus PBDs at the reduced rates paid to nonexcepted off-campus PBDs. The commenters asserted that CMS is ignoring the express and statutorily mandated grandfathering exception created by section 603.

Response: We believe the changes required by section 603 of the Bipartisan Budget Act of 2015 made in section 1833(t) of the Act address some of the concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting for new off-campus PBDs after November 1, 2015. However, the majority of hospital off-campus departments continue to receive full OPPS payment (including off-campus emergency departments and excepted off-campus departments of a hospital), which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. Therefore, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service, which results in higher costs for the Medicare program, beneficiaries, and taxpayers more generally. We interpret our authority under section 1833(t)(2)(F) of the Act to allow us to implement our proposed method of applying an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at off-campus PBDs, even those that are excepted from section 1833(t)(21) of the Act. We believe that this is an appropriate method because the clinic visit service is the same service furnished in excepted and nonexcepted off-campus PBDs.

When Congress passed the Bipartisan Budget Act of 2015, Medicare OPPS expenditures were $56 billion and growing at an annual rate of about 7.3 percent. In addition, the percentage increase in volume and intensity of outpatient services was increasing at 3.4 percent. For the upcoming 2019 calendar year, we estimate that, without this policy, OPPS expenditures would be $74.5 billion, growing at a rate of 9.1 percent, with the volume and intensity of outpatient services increasing at 5.4 percent, based on the Midsession Review for 2019. While it is clear that the action Congress took in 2015 to address certain off-campus PBDs helped stem the tide of these increases in the volume of OPD services, it is likewise clear that the more specific payment adjustment has not adequately addressed the overall increase in the volume of these types of OPD services because most off-campus PBDs continue to be paid the higher OPPS amount for these services. We would not be able to adequately address the unnecessary increases in the volume of clinic visits in HOPDs if we did not apply this policy to all off-campus HOPDs. We do not believe that the section 603 amendments to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted off-campus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS.

Comment: Several commenters believed that CMS does not have statutory authority to implement this policy in a nonbudget neutral manner. The commenters explained that, because CMS lacks the authority to reduce clinic visit payment rates as a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act, that provision cannot provide authority for the

[79] Available at: *https://www.gao.gov/assets/680/674347.pdf.*

payment reduction to be made in a nonbudget neutral way. The commenters also claimed that the only nonbudget neutral option available to the agency is to adjust the conversion factor in a subsequent year, as provided under section 1833(t)(9)(C) of the Act. The commenters argued that if Congress had intended to give CMS the authority to make a volume control method nonbudget neutral, it would have done so in clearer and more express terms. Other commenters stated that if this policy is finalized, it should be done so only in a budget neutral manner.

Response: We maintain that while section 1833(t)(9)(B) of the Act does require that certain changes made under the OPPS be made in a budget neutral manner, this provision does not apply to the volume control method under section 1833(t)(2)(F) of the Act as outlined through our proposal. As we noted in the proposed rule (83 FR 37138 through 37143), unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a ''method'' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not include such a requirement. Therefore, we maintain that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) of section 1833(t) of the Act that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year. We continue to interpret this provision to mean that the Secretary will have implemented a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented. Further, as we stated in the proposed rule (83 FR 37138 through 37143), we believe that implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume within the OPPS system in the aggregate.

Comment: Several commenters supported the recommendation from the HOP Panel not to implement this proposal and to instead study the matter to better understand the reasons for increased utilization.

Response: Section 1833(t)(9)(A) of the Act provides that the Secretary shall consult with the Panel on policies affecting the clinical integrity of the ambulatory payment classifications and their associated weights under the OPPS. The Panel met on August 20, 2018 and made recommendations on this proposed policy, and we consulted with the Panel on those recommendations. The HOP Panel's recommendations, along with public comments on provisions of the proposed rule, have been taken into consideration in the development of this final rule with comment period. While we are not accepting the HOP Panel's recommendation to not implement this proposal, we will continue to monitor and study the utilization of outpatient services as recommended by the Panel.

Comment: Several commenters expressed concern that this policy proposal would disproportionately affect safety net hospitals and rural providers. Numerous commenters representing providers and beneficiaries in the State of Washington expressed concerned about the impact this proposal would have on their area. Several commenters also requested that sole community hospitals (urban and rural), rural referral centers, and Medicare-dependent hospitals be exempted from this policy. A number of commenters, including many State hospital associations, expressed concern that the magnitude of the proposed payment reduction would have a drastic effect on their margins and endanger the investments many hospitals have made in their provider-based facilities. In addition, commenters suggested that the reduction in payment would ultimately lead to a reduction of services that would adversely affect vulnerable patient populations. One commenter conducted a trend analysis and found that 200 hospitals would shoulder 73 percent of the proposed payment reduction. According to this commenter's analysis, for the 200 hospitals most affected by this proposal, the average reduction would be 5.5 percent. For the remaining hospitals, the average reduction would be 0.5 percent.

Response: We share the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges for rural providers. Across the various Medicare payment systems, CMS has implemented a number of special payment provisions for rural providers to maintain access and deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural sole community hospitals. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural sole community hospitals of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006. In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we sought public comment on how we might account in the future for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas. In addition, we sought public comment on whether there should be exceptions from this policy for rural providers, such as those providers that are at risk of hospital closure or those providers that are sole community hospitals. Taking into consideration the comments regarding rural hospitals, we believe that implementing this policy with a 2-year phase-in will help to mitigate the immediate impact on rural hospitals. We may revisit this policy to consider potential exemptions in the CY 2020 OPPS rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act

(departments that bill the modifier ''PO'' on claim lines). In addition, we are finalizing our proposal to implement this policy in a nonbudget neutral manner. We will continue to monitor the impacts of this policy as it is phased in to ensure that beneficiaries continue to have access to quality care.

In response to public comments we received, we will be phasing in the application of the reduction in payment for HCPCS code G0463 in this setting over 2 years. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service. The final payment rates are available in Addendum B to this final rule with comment period (which is available via the internet on the CMS website). The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2019. Based on a 2-year phase-in of this policy, half of the total 60-percent payment reduction, a 30-percent reduction, will apply in CY 2019. In other words, these departments will be paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30-percent payment reduction that applies in CY 2019) for the clinic visit service in CY 2019. In CY 2020, these departments will be paid the site-specific PFS rate for the clinic visit service. We note that by phasing in this policy over 2 years, the estimated savings associated with this policy will change. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated CY 2019 savings of approximately $380 million, with approximately $300 million of the savings accruing to Medicare, and approximately $80 million saved by Medicare beneficiaries in the form of reduced copayments. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

While we are exploring developing a method to systematically control for unnecessary increases in the volume of other hospital outpatient department services that we may propose in future rulemaking, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. In the CY 2019 OPPS/ASC proposed rule (83 FR 37143), we solicited public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.

In addition, we solicited public comments on how to expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in the utilization of OPD services. Therefore, we sought public comment on the following:

- How might Medicare define the terms ''unnecessary'' and ''increase'' for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness, and patient demographics?
- While we proposed to pay the site-specific PFS payment rate for clinic visits beginning in CY 2019, we also were interested in other methods to control for unnecessary increases in the volume of outpatient services. Prior authorization is a requirement that a health care provider obtain approval from the insurer prior to providing a given service in order for the insurer to cover the service. Private health insurance plans often require prior authorization for certain services. Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- Several private health plans use utilization management as a cost-containment strategy. How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?
- How should we account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

We received feedback on a variety of issues in response to the comment solicitation on additional future considerations. These comments are summarized below.

Comment: In response to the solicitation on how CMS might expand the application of the Secretary's statutory authority under section 1833(t)(2)(F) of the Act to additional items and services paid under the OPPS that may represent unnecessary increases in OPD volume, MedPAC suggested that CMS consider using the five criteria that MedPAC has developed for identifying services for which it is reasonable to have site-neutral payments between freestanding physician offices and HOPDs.[80]

In response to the solicitation on whether prior authorization should be considered as a method for controlling overutilization of services, most commenters believed that, while prior authorization may be a good method for controlling overutilization of services, it can also lead to increased administrative burden and inhibit patient access. One commenter suggested that CMS consider applying prior authorization for providers with service volumes that are statistical outliers or for those whose ordering rates are not in compliance with clinical guidelines.

In response to the comment solicitation on when it might be appropriate to pay a higher OPPS payment rate for a service that can be performed safely in a lower cost setting, several commenters believed that it would be appropriate to pay a higher OPPS rate for services that can be performed in a lower cost setting if providing this higher payment can improve patient experience, efficiency, and quality of care. Several commenters also mentioned that the comprehensive care management and coordination that accompanies receiving services at an off-campus PBD of a hospital might justify the higher OPPS payment rate. Commenters also asserted that the additional certifications required for services furnished in PBDs compared to services furnished in physician offices justify a higher payment rate.

In response to the comment solicitation on utilization management, several commenters were opposed to this concept and stated that utilization management would increase provider burden and delay patient access to care. One commenter supported the concept

[80] Medicare Payment Advisory Commission. 2013. Report to the Congress: Medicare and the health care delivery system. Washington, DC: MedPAC.

of utilization management, but believed that it must be based on clinical validity, support the continuity of patient care, be transparent and fair, provide timely access to care and administrative efficiency, and provide alternatives and exemptions to those clinicians with appropriate utilization rates. Other commenters supported appropriate use criteria and evidence-based clinical guidelines and pathways as effective clinical-decision support tools to assist clinicians and hospitals in the reduction of potentially harmful or rarely appropriate services.

Response: We thank commenters for their responses to our comment solicitation. We will consider these comments for future rulemaking.

C. Application of the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital

1. Historical Perspective

a. Section 603 of the Bipartisan Budget Act of 2015

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. Accordingly, we refer to an ''off-campus outpatient department of a provider,'' which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an ''off-campus outpatient provider-based department'' or an ''off-campus PBD.'' For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

b. Applicable Payment System

As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143 through 37144), to implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the Medicare PFS as the ''applicable payment system'' that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. As we discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79718) and reiterated in the CY 2018 PFS final rule with comment period (82 FR 53028), payment for Medicare Part B drugs that would be separately payable under the OPPS (assigned a status indicator of ''K''), but are not payable under the OPPS because they are furnished by nonexcepted off-campus PBDs, is made in accordance with section 1847A of the Act (generally, at a rate of ASP+6 percent), consistent with Part B drug payment policy for items or services furnished in the physician office (nonfacility) setting. We did not propose or make an adjustment to payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, but indicated we may consider doing so through future notice-and-comment rulemaking.

In the interim final rule with comment period that accompanied the CY 2017 OPPS/ASC final rule with comment period, we established payment policies under the Medicare PFS for nonexcepted items and services furnished by a nonexcepted off-campus PBD on or after January 1, 2017. In accordance with sections 1848(b) and (c) of the Act, Medicare PFS payment is based on the relative value of the resources involved in furnishing particular services (81 FR 79790). Resource-based relative values are established for each item and service (described by a HCPCS code(s)) based on the work (time and intensity), practice expense (such as clinical staff, supplies and equipment, office rent, and overhead), and malpractice expense required to furnish the typical case of the service. Because Medicare makes separate payment under institutional payment systems (such as the OPPS) for the facility costs associated with many of the same services that are valued under the PFS, we establish two different PFS payment rates for many of these services—one that applies when the service is furnished in a location where a facility bills and is paid for the service under a Medicare payment system other than the PFS (the facility rate), and another that applies when the billing practitioner or supplier furnishes and bills for the entire service (the nonfacility rate). Consistent with the long-established policy under the PFS to make payment to the billing practitioner at the facility rate when Medicare makes a corresponding payment to the facility (under the OPPS, for instance) for the same service, physicians and nonphysician practitioners furnishing services in nonexcepted PBDs continue to report their services on a professional claim form and are paid for their services at the PFS facility rate.

Similarly, there are many (mostly diagnostic) services paid under the PFS that have two distinct portions of the service: A technical component (TC) and a professional component (PC). These components can be furnished independently in time or by different suppliers, or they may be furnished and billed together as a ''global'' service (82 FR 52981). Payment for these services can also be made under a combination of payment systems; for example, under the PFS for the professional component and the OPPS for the facility portion. For instance, for a diagnostic CT scan, the technical component relates to the portion of the service during which the image is captured and might be furnished in an office or HOPD setting, and the professional component relates to the interpretation and report by a radiologist.

In the CY 2017 interim final rule with comment period, we stated that we continue to believe that it is operationally infeasible for nonexcepted off-campus PBDs to bill directly under the PFS for the subset of PFS services for which there is a separately valued technical component (81 FR 79721). In addition, we explained that we believe hospitals that furnish nonexcepted items and services are likely to furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. We stated that we therefore believe it is necessary to establish a new set of payment rates under the PFS that reflect the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS that is specific to one site of service (the off-campus PBD of a hospital) with the packaging (bundling) rules that are significantly different from current PFS rules (81 FR 79721).

In continuing to implement the requirements of sections 1833(t)(1)(B) and (t)(21) of the Act, we recognize that

there is no established mechanism for allowing hospitals to report and bill under the PFS for the portion of resources incurred in furnishing the full range of nonexcepted items and services. This is because hospitals with nonexcepted off-campus PBDs that furnish nonexcepted items and services generally furnish a broader range of services than other provider or supplier types for which there is a separately valued technical component under the PFS. As such, we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting.

Nonexcepted off-campus PBDs continue to bill for nonexcepted items and services on the institutional claim utilizing a new claim line (modifier ''PN'') to indicate that an item or service is a nonexcepted item or service. For a detailed discussion of the current PFS relativity adjuster related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637), the CY 2018 PFS final rule with comment period (82 FR 53019 through 53025), and the CY 2019 PFS proposed rule.

c. Section 340B of the Public Health Service Act

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37144 through 37145), the 340B Program, which was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992, is administered by the Health Resources and Services Administration (HRSA) within HHS. The 340B Program allows participating hospitals and other health care providers to purchase certain ''covered outpatient drugs'' (as defined under section 1927(k) of the Act and interpreted by HRSA through various guidance documents) at discounted prices from drug manufacturers.

In the CY 2018 OPPS/ASC proposed rule (82 FR 33632 through 33635), we proposed changes to the payment methodology under the OPPS for separately payable drugs and biologicals acquired under the 340B Program. We stated that these changes would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur. Such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs that are purchased under the 340B Program to Medicare beneficiaries. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period, we finalized our proposal that separately payable, covered outpatient drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program will be paid ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. CAHs are not subject to this 340B policy change because they are paid under section 1834(g) of the Act. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the alternative payment methodology for 340B-acquired drugs and biologicals. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or to vaccines, which are excluded from the 340B Program.

2. Proposal and Final Policy To Pay an Adjusted Amount for 340B-Acquired Drugs and Biologicals Furnished in Nonexcepted Off-Campus PBDs in CY 2019 and Subsequent Years

As noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79716), prior to the implementation of the payment adjustment under the OPPS for drugs and biologicals acquired under the 340B program, separately payable drugs and biologicals were paid the same rate at both excepted and nonexcepted off-campus departments of a hospital. The policy we finalized in the CY 2018 OPPS/ASC final rule with comment period, in which we adjusted the payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from ASP+6 percent to ASP minus 22.5 percent, applies to separately payable drugs and biologicals paid under the OPPS (81 FR 59353 through 59369). Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, in accordance with our policy in effect as of CY 2018, nonexcepted items and services furnished by nonexcepted off-campus PBDs are no longer covered outpatient department services and, therefore, are not payable under the OPPS. This means that nonexcepted off-campus PBDs are not subject to the payment changes finalized in the CY 2018 OPPS/ASC final rule with comment period that apply to hospitals and PBDs paid under the OPPS. Because the separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off-campus PBDs are no longer covered outpatient department services, as of CY 2018, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings—typically at ASP+6 percent—regardless of whether they are acquired under the 340B Program.

The current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In establishing these policies in prior rulemaking, we pointed out that the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the

PFS localities, which reflect cost differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician's office setting at ASP+6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a per-day cost exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in section V.A.1. of the CY 2019 OPPS/ASC proposed rule, section 1847A of the Act establishes the ASP methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC, and the AWP (82 FR 59337). As noted in section V.B.2.b. of the CY 2019 OPPS/ASC proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350). Consequently, in the case of services furnished in a hospital outpatient department, Medicare pays ASP+6 percent for separately payable Part B drugs and biologicals unless those drugs or biologicals are acquired under the 340B Program, in which case they are paid at ASP minus 22.5 percent. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59343 through 59371).

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37146), as a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately payable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term ''applicable payment system,'' we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59354), several recent studies and reports on Medicare Part B payments for 340B-acquired drugs highlight a difference in Medicare Part B drug spending between 340B hospitals and non-340B hospitals as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost. When we initially developed the policy for nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid, both in the OPPS and in other Part B settings, such as physician offices, through similar methodologies under section 1847A/1842(o) of the Act. For drugs and biologicals that are packaged in the OPPS, we adopted similar packaging payment policies for purposes of making the site-specific payment under the PFS for nonexcepted off-campus PBDs. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment exclusively for these departments would present a significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted PBD or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs and biologicals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. In light of the significant drug payment differences between excepted and nonexcepted off-campus PBDs, in combination with the potential eligibility for discounts, which result in reduced costs under the 340B Program for both kinds of departments, our current payment policy could undermine the validity of the use of the OPPS payment structure in nonexcepted off-campus PBDs. In order to avoid such perverse incentives and the potential resulting distortions in drug payment, in the CY 2019 OPPS/ASC proposed rule (83 FR 37146), we proposed, pursuant to our authority at section 1833(t)(21)(C) of the Act, to identify the PFS as the ''applicable payment system'' for 340B-acquired drugs and biologicals and, accordingly, to pay under the PFS instead of under section 1847A/1842(o) of the Act an amount equal to ASP minus 22.5 percent for drugs and biologicals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs. We stated in the proposed rule that we believe this proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, depending upon whether they are furnished by excepted off-campus PBDs or nonexcepted off-campus PBDs, which we believe is an unnecessary difference in payment where the 340B Program does not differentiate between PBDs paid under the OPPS and PBDs paid under the PFS using the PFS relativity adjuster.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59367 through 59368), we discussed public comments that we received that noted that the alternative payment methodology for 340B-acquired drugs and biologicals did not apply to nonexcepted off-campus PBDs of a hospital and could result in behavioral

changes that may undermine CMS' policy goals of reducing beneficiary cost-sharing liability and undercut the goals of section 603 of Public Law 114–74. Commenters recommended that, if CMS adopted a final policy to establish an alternative payment methodology for 340B drugs in CY 2018, CMS also apply the same adjustment to payment rates for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program (82 FR 59367). While we did not propose to adjust payment for 340B-acquired drugs in nonexcepted off-campus PBDs in CY 2018, we indicated that we would consider adopting such a policy in future rulemaking.

We agree with commenters that the difference in the payment amounts for 340B-acquired drugs furnished by hospital outpatient departments, excepted off-campus PBDs versus nonexcepted off-campus PBDs, creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37145), we proposed changes to the Medicare Part B drug payment methodology for drugs and biologicals furnished and billed by nonexcepted off-campus departments of a hospital that were acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, we proposed to pay under the PFS the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital. Furthermore, we proposed to except rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from this payment adjustment (83 FR 37145). We stated that we believe that our proposed payment policy would better reflect the resources and acquisition costs that nonexcepted off-campus PBDs incur for these drugs and biologicals.

Comment: Some commenters, including organizations representing physician oncology practices, orthopaedic surgeons, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices, physician organizations, and health insurers, supported the proposal. Some of these commenters commended CMS for its proposal, which they believed would help address the growth of the 340B Program, stem physician practice consolidation with hospitals, preserve patient access to community-based care, and address the significant incongruity between the payment amounts for 340B-acquired drugs, depending upon the setting in which they are furnished. One of these commenters, a pharmaceutical company, stated that the 340B Program has grown beyond its original intent and needs to be refocused to better meet the needs of vulnerable patients. The commenter noted that there is an incentive to inappropriately shift administration of drugs from excepted to nonexcepted off-campus PBDs for the purpose of securing higher payment. In addition, the commenter urged HHS to adopt policies ''that prevent the unjustified expansion of the 340B program to unintended populations through contract pharmacies, child sites, and individuals who Congress did not intend to be considered 340B patients.''

A few commenters, including organizations representing community oncology practices, stated that the opportunity for 340B-participating hospitals to get substantial revenue from cancer drugs has created financial incentives for hospitals to expand oncology services, notably through the acquisition of independent community oncology practices. Furthermore, one of these commenters asserted that, when these facilities purchased by 340B-participating entities become off-campus PBDs, they also become eligible for 340B Program discounts, thus ''further fueling the program's staggering growth.'' These commenters cited a report that states that, over the last decade, 658 community oncology practices have been acquired by hospitals, and 3 out of 4 of these acquisitions were by hospitals already eligible for the 340B Program. Accordingly, these commenters believe that the growth of Part B drug spending in recent years has been disproportionately driven by higher payments in the hospital outpatient setting. Another commenter asserted that the current situation creates two undesirable incentives. First, it creates an incentive for physicians to join a hospital to furnish the same types of services that could have been furnished in the physician office setting, thereby increasing costs to the Medicare program, Medicare beneficiaries, and taxpayers without any associated increase in access to care for Medicare beneficiaries, particularly low-income beneficiaries. Second, it encourages hospitals to move services off the hospital campus for financial incentives.

Some commenters urged CMS and HRSA to work with Congress to reform the 340B Program. One commenter recommended that CMS gather additional data to better understand 340B Program acquisition costs and the impact of payment reductions on 340B Program providers. In addition, a few commenters recommended that CMS revise the definition of ''patient'' to reflect the program's original intent.

Response: We thank commenters for their support and recommendations. We agree with the commenters that the difference in the payment amounts for 340B-acquired drugs furnished by different types of hospital outpatient departments, excepted off-campus PBDs versus nonexcepted off-campus PBDs, creates an incentive for hospitals to move drug administration services for 340B-acquired drugs to nonexcepted off-campus PBDs to receive a higher payment amount for these drugs, thereby undermining our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. Therefore, we continue to believe that our proposed policy will better align Medicare payment for separately payable drugs acquired under the 340B Program with the actual resources expended to acquire such drugs in nonexcepted off-campus PBDs of a hospital.

As we previously stated, CMS does not administer the 340B Program. Accordingly, comments related to eligibility for the 340B Program as well as 340B Program policies are outside the scope of the proposed rule and are not addressed in this final rule with comment period.

Comment: One commenter, who cited studies conducted by the GAO, OIG, and MedPAC, suggested that CMS make additional downward adjustments to drug payments under the 340B Program in future years because the 22.5 percent payment reduction ''was conservative'' and the actual average discount experienced by 340B hospitals is likely much higher than 22.5 percent. The commenter asserted that 22.5 percent reflects the average minimum discount that 340B hospitals receive for drugs acquired under the program, and that discounts across all 340B providers average 33.6 percent of ASP.

Response: We thank the commenter for this feedback. We will continue to

analyze the data on these drugs for future rulemaking. As we mentioned in the CY 2019 OPPS/ASC proposed rule, we share the commenter's concern that current Medicare payments for drugs acquired by nonexcepted off-campus PBDs are well in excess of the overhead and acquisition costs for drugs purchased under the 340B Program. We also continue to believe that Medicare beneficiaries should be able to benefit from the significant discounts hospitals receive on 340B-acquired drugs through reduced copayments.

Comment: One commenter, an organization representing children's hospitals, supported the proposal to except children's hospitals from the proposed payment policy for drugs purchased under the 340B Program. However, the commenter asserted that children's hospitals are undercompensated by government programs, and that a recent report found that the overall Medicare margin for all hospitals is negative. Furthermore, the commenter stated that, while self-governing children's hospitals are excepted from the payment policy, children's hospitals within academic medical centers or health care systems remain subject to this policy, which will curtail the ability of such children's hospitals to care for needy children. The commenter urged CMS not to apply this policy to children's hospitals within academic medical centers or health care systems.

Response: We thank the commenter for its support and feedback. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59366), because of how children's hospitals are paid under the OPPS, we acknowledged that the 340B drug payment policy may not result in reduced payments for these hospitals in the aggregate. While the payment policy we are establishing in this final rule with comment period applies to nonexcepted departments of a hospital that are paid under the PFS rather than the OPPS, we believe that adopting an analogous policy, regardless of status, is prudent so that a generally excepted hospital receives payment for drugs in the same manner, regardless of the status (excepted or nonexcepted) of each PBD of the hospital.

In addition, it is unclear from the comment whether the referenced children's hospitals ''within academic medical centers or health care systems'' are enrolled in the Medicare program as children's hospitals or whether they are simply a department of an enrolled hospital provider. However, any separately enrolled children's hospital that is paid as such is exempt from the 340B-acquired drug payment reduction, while children's units that are not separately enrolled would not be exempt from the 340-acquired drug payment policy.

Comment: A few commenters, including organizations representing sole community hospitals, supported the proposal to extend the exception for rural sole community hospitals from the proposed 340B Program payment adjustment. However, these commenters remained concerned that other vulnerable hospitals continue to be subject to the 340B Program payment reduction. Accordingly, these commenters recommended that CMS exempt urban sole community hospitals, Medicare-dependent hospitals, and hospitals with rural referral center status from the payment adjustment. In addition, rural hospitals recommended that rural providers be permanently excepted from this policy.

Response: We share commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. Consequently, for CY 2019, we are excluding rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes) from this policy. However, we do not believe that a payment exemption for nonexcepted off-campus departments of urban SCHs is necessary because these hospitals are not exempted from the 340B payment policy for hospital departments paid under the OPPS. Nonetheless, we will continue to analyze the data for these hospitals to determine whether urban SCHs should be exempt from this payment policy, as well as whether permanent exemption for rural SCHs is warranted in future rulemaking.

With respect to rural referral centers, in the CY 2018 OPPS/ASC final rule with comment period, we noted that there is no special payment designation for rural referral centers under the OPPS. By definition, rural referral centers must have at least 275 beds and therefore are larger relative to rural sole community hospitals. In addition, rural referral centers are not subject to a distance requirement from other hospitals. Accordingly, rural referral centers are neither as small (in terms of bed size) or as isolated (in terms of proximity to other hospitals) as rural SCHs, nor are they generally eligible for special payment status under the OPPS, and we do not believe that a payment exemption from this policy for these centers is warranted.

Furthermore, as stated earlier in this section, we believe that we should adopt an analogous payment policy across hospital settings, regardless of the status of each PBD. Because we did not exempt grandfathered off-campus PBDs with MDH classification from the 340B payment adjustment in CY 2018, we do not believe that nonexcepted off-campus PBDs with Medicare-dependent hospital status should be exempted at this time. Therefore, for CY 2019, Medicare-dependent hospitals will not be exempt from this payment policy.

For CY 2019, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals will be excepted from the alternative payment methodology for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs, and therefore will be required to bill under the PFS using the institutional claim form and report the informational modifier ''TB'' for 340B-acquired drugs and biologicals. These providers will continue to be paid ASP+6 percent for 340B-acquired drugs and biologicals under the PFS. In addition, as we stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or to vaccines, which are excluded from the 340B Program.

We note that this policy does not alter covered entities' access to the 340B Program. The expansion of the alternative 340B drug payment methodology solely changes Medicare payment for drugs furnished in nonexcepted off-campus PBDs of a hospital if such drugs were acquired under the 340B Program. We may revisit our policy regarding exceptions to the 340B drug payment reduction in the CY 2020 OPPS/ASC rulemaking.

Comment: In its comment, MedPAC reiterated recommendations included in its March 2016 Report to Congress. In this report, MedPAC recommended that payment rates for all separately payable drugs provided in a 340B hospital be reduced by 10 percent of the current payment rate of ASP+6 percent (resulting in ASP minus 5.3 percent after taking application of the sequester into account). MedPAC noted that its March 2016 report also included a recommendation to Congress that

savings from the reduced payment rates be directed to the Medicare-funded uncompensated care pool, which would target hospitals providing the most care to the uninsured and in that way benefit indigent patients, and that payments be distributed in proportion to the amount of uncompensated care that hospitals provide. MedPAC believed that legislation would be needed to direct drug payment savings to the uncompensated care pool and noted that current law requires the savings to be retained with the OPPS to make the payment system budget neutral. MedPAC encouraged the Secretary to work with Congress to enact legislation necessary to allow MedPAC's recommendation to be implemented, if such a recommendation could not be implemented administratively. MedPAC further noted that legislation would also allow Medicare to apply the policy to all OPPS separately payable drugs, including those on pass-through payment status. Accordingly, MedPAC recognized that CMS does not have the legal authority to implement its March 2016 recommendation and shares CMS' concern that the lack of site-neutral payments may cause a shift in administration of nonpass-through separately payable drugs to nonexcepted off-campus PBDs. Additionally, MedPAC stated that CMS should ensure that payment for 340B-acquired drugs is equal across settings.

Response: We thank MedPAC for its support and feedback. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59364 through 59365), we do not believe that reducing the Medicare payment rate by only 10 percentage points below the current payment rate of ASP+6 percent (that is, ASP minus 4 percent) would better reflect the acquisition costs incurred by 340B-participating hospitals.

We note that we responded to a similar public comment in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59364 through 59365) and refer readers to a summary of that comment and our response.

Comment: Many commenters stated that the Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs acquired in off-campus PBDs, and contended that the expansion of the 340B payment policy at nonexcepted off-campus PBDs would ''effectively eviscerate'' the 340B Program. These commenters further noted that extending the Medicare payment cuts to nonexcepted off-campus PBDs would greatly undermine 340B hospitals' ability to continue programs designed to improve access to services.

One commenter, an organization representing over 1,300 public and nonprofit providers enrolled in the 340B Program, argued that since the 340B payment policy took effect in January 2018, many hospitals have experienced financial and operational challenges, including staff reductions, fewer free or discounted drugs for patients, clinic and pharmacy closures, and reductions in services provided. The commenter opposed the 340B payment proposal for a number of reasons, primarily because the commenter believed that the current OPPS 340B payment rate harms hospitals' ability to treat low-income patients and the proposals to continue and expand the cuts would worsen the impact. Furthermore, the commenter argued that CMS' proposed payment reduction does not reduce patient costs or Medicare spending or address ''skyrocketing drug prices''; CMS' payment reduction violates the 340B statute; CMS' payment reduction violates the Medicare statute; and CMS' payment reduction relies on a ''faulty premise that fails to recognize that 340B hospitals serve patients with more expensive medical needs.'' The commenter further asserted that Congress, as well as ''one-hundred percent of hospitals,'' have expressed concern about the payment reduction's impact on 340B providers' ability to serve their patients.

Many additional commenters, including some hospital associations, contended that CMS does not have the legal authority to apply the OPPS Medicare payment rate to nonexcepted off-campus PBDs in 340B-participating hospitals because section 1833(t)(21)(C) of the Act does not authorize CMS to pay at a rate that is less than the rate paid under the selected ''applicable payment system.'' Specifically, a few commenters asserted that payment for these drugs and biologicals is determined pursuant to the rules of section 1842(o)(1)(C) of the Act, which mandates that payment is to be made for these drugs and biologicals when furnished by nonexcepted off-campus PBDs pursuant to the rules of section 1847A of the Act.

Response: We do not believe that the proposed payment policy violates section 340B of the Public Health Service Act or the Social Security Act. There is no requirement in the Public Health Service Act that drugs or biologicals acquired under the 340B Program generate a profit margin for hospitals through Medicare payments, and there is no requirement in any part of section 1833(t) of the Social Security Act to pay a particular minimum rate for a hospital enrolled in the 340B Program. Further, we disagree with the commenter's assertion that CMS' payment reduction does not reduce patient costs or Medicare spending. Based on our proposed adjustment for CY 2019, we estimated that the Medicare Program and beneficiaries would save approximately $49 million under the PFS.

We also disagree with commenters who believe that the OPPS payment rate for 340B-acquired drugs will ''effectively eviscerate'' the 340B Program as well as the implication that extending the same rate that applies to 340B-acquired drugs and biologicals furnished by hospital departments under the OPPS to nonexcepted off-campus PBDs will perpetuate that concern. The findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. Indeed, in some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program (OIG November 2015, Report OEI–12–14–00030, page 9). As stated in the CY 2018 final rule with comment period, we believe that ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs, and that even with the reduced payments, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program. We also have noted that 340B Program participation does not appear to be well aligned with the provision of uncompensated care, as some commenters suggested (82 FR 59359).

Payment under the ''applicable payment system'' pursuant to section 1833(t)(21)(C) of the Act is made under the PFS for most services, including for the many drugs that are packaged under the OPPS, using a PFS relativity adjuster that is applied to the OPPS payment rate. As such, the PFS payment for nonexcepted items and services in nonexcepted off-campus PBDs is made on a prospective payment basis, and we are therefore not required to make payment under section 1847A/1842(o) of the Act for those packaged drugs, many of which would be separately payable under the PFS. Further, as we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37145), the current PFS payment policies for nonexcepted items and services incorporate a significant number of payment policies and adjustments made under the OPPS (81 FR 79726; 82 FR 53024 through 53025). In establishing these policies in prior rulemaking, we pointed out that

the adoption of these policies was necessary in order to maintain the integrity of the PFS relativity adjuster because it adjusts payment rates developed under the OPPS (81 FR 79726). For example, it is necessary to incorporate OPPS packaging rules into the site-specific PFS rate because the PFS relativity adjuster is applied to OPPS rates that were developed based on those packaging rules. In addition, many of the OPPS policies and adjustments are replicated under the nonexcepted off-campus PBD site-specific PFS rates because they are specifically applicable to hospitals as a setting of care. For example, we adopted the geographic adjustments used for hospitals instead of the adjustments developed for the PFS localities, which reflect cost differences calculated for professionals and suppliers rather than hospitals (81 FR 79726).

Since we have adopted the payment adjustment under the OPPS for 340B-acquired separately payable drugs, we have become concerned that there would be a perverse incentive for hospitals to circumvent the OPPS payment adjustment by furnishing 340B-acquired drugs in nonexcepted off-campus PBDs where Medicare currently makes payment for those drugs at ASP+6 percent. To avoid this payment incongruity and perverse incentive, we proposed to designate the PFS as the ''applicable payment system'' for 340B-acquired separately payable drugs furnished in nonexcepted off-campus PBDs, and to make payment at the OPPS-comparable rate.

Comment: A few commenters asserted that, while CMS estimated that the payment change would result in a payment cut of $48.5 million in CY 2019, CMS provided no data to support this estimate and failed to provide sufficient access to data, its methodology, or its analysis to allow the public to assess and replicate the proposed CY 2019 340B payment policy. One commenter recommended that CMS delay extension of the 340B payment policy until more information is available related to the impact on Medicare beneficiaries.

Many commenters opposed reducing payments to hospitals for 340B drugs in a nonbudget-neutral manner and instead suggested that such policy be implemented in a budget neutral manner as was implemented in the CY 2018 OPPS/ASC final rule with comment period. In addition, some commenters recommended that CMS annually calculate a budget neutral adjustment for the 340B policy, as the approach is consistent with other budget neutral policies included in the OPPS.

Response: We thank the commenters for their input. We disagree that this policy should be implemented in a budget neutral manner because the payments made to nonexcepted off-campus departments of a hospital are not paid under the OPPS. As we stated in the CY 2019 OPPS/ASC proposed rule, to develop an estimated impact of this proposal, we analyzed the CY 2017 outpatient claims data used in ratesetting for the CY 2019 proposed rule. Based on the most recent claims data from CY 2017 reporting, we found 117 unique nonexcepted off-campus PBDs associated with 340B hospitals that billed for status indicator ''K'' drugs. Their ''K'' billing represents approximately $182.5 million in Medicare payments based on a payment rate of ASP+6 percent. Based on our proposed adjustment, for CY 2019, we estimated that the Medicare Program and beneficiaries would save approximately $49 million under the PFS. Regarding budget neutrality requirements, we note that when we initially developed the payment policy for nonexcepted items and services furnished by nonexcepted off-campus PBDs, most separately payable drugs and biologicals were paid at the same rates specified under section 1847A/1842(o) of the Act (generally, ASP+6) when furnished in the HOPD and in other outpatient settings, such as physician offices. When we initially established the ASP methodology under section 1847A/1842(o) of the Act as the ''applicable payment system'' for separately payable drugs under section 1833(t)(21)(C) of the Act, there was no applicable budget neutrality requirement. For the proposed change in CY 2019 to establish the PFS as the applicable payment system for separately payable 340–B-acquired drugs furnished by nonexcepted off-campus PBDs, we believe the site-specific PFS payment for these drugs and biologicals represents new utilization under the PFS and would, consequently, not be subject to the PFS budget neutrality requirements under 1848(c) of the Act for CY 2019. We will consider any applicable budget neutrality requirements regarding the site-specific payment under the PFS for future rulemaking.

Comment: Numerous commenters argued that reducing payments for 340B-acquired drugs could encourage hospitals to selectively purchase certain drugs at higher prices outside of the 340B Program to maximize revenue. One of these commenters recommended the implementation of alternate reimbursement methodologies for 340B-purchased drugs, such as a 6 percent add-on payment to the product-specific estimated 340B cost, in order to discourage hospitals from selectively purchasing some drugs outside of the 340B Program (resulting in ASP minus 16.5 percent after taking application of the add-on payment into account).

Response: While participation in the 340B Program has always been voluntary and hospitals have always had the ability to choose to purchase drugs outside the 340B Program, we do not see the relevance of these points to our proposed policy. That is, the policy we proposed with respect to payment for 340B-acquired drugs in nonexcepted departments for CY 2019 simply aligns with the policy already established for 340B-acquired drugs under the OPPS for CY 2018. In addition, as we explained in CY 2018 OPPS rulemaking, the payment rate of ASP minus 22.5 percent is better aligned with the average resources to acquire a 340B drug, and therefore, we do not believe that a higher payment rate for 340B-acquired drugs in nonexcepted departments is warranted.

We thank the commenters for their feedback. After consideration of the public comments we received, we are finalizing our proposal, without modification, to make payment for separately payable 340B-acquired drugs furnished by nonexcepted off-campus departments of a hospital under the PFS, and to establish the payment rate for those drugs at ASP minus 22.5 percent. This policy is expected to lower the cost of drugs and biologicals for Medicare beneficiaries and ensure that they benefit from the discounts provided through the program, and to do so more equitably across HOPD settings.

In summary, for CY 2019, in accordance with section 1833(t)(21)(C) of the Act and our established 340B payment methodology as described in the CY 2018 OPPS/ASC final rule with comment period, separately payable Part B drugs and biologicals (assigned status indicator ''K''), other than vaccines and drugs with pass-through payment status, that are acquired through the 340B Program or through the 340B PVP at or below the 340B ceiling price will be paid at a rate of ASP minus 22.5 percent when billed by a hospital that is not excepted from the payment adjustment. Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator ''L'' or ''M'') and drugs and biologicals with transitional pass-through payment status (assigned status indicator ''G'').

Medicare will continue to pay for drugs and biologicals that are not purchased with a 340B Program discount at ASP+6 percent.

To effectuate the payment adjustment for 340B-acquired drugs and biologicals, CMS implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS (other than a type of hospital excluded from the OPPS or excepted from the 340B drug payment policy for CY 2019) and, beginning January 1, 2019, nonexcepted off-campus PBDs of a hospital paid under the PFS, are required to report modifier ''JG'' on the same claim line as the drug or biological HCPCS code to identify a 340B-acquired drug or biological. For CY 2019, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. These hospitals will be required to report informational modifier ''TB'' for 340B-acquired drugs and biologicals, and will continue to be paid ASP+6 percent.

D. Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

1. Background

a. Section 603 of the Bipartisan Budget Act of 2015

We refer readers to section X.C.1.a. of the CY 2019 OPPS/ASC proposed rule (83 FR 37143) for a discussion of the provisions of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), as implemented in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719). As discussed in the CY 2017 OPPS/ASC final rule with comment period, we adopted the PFS as the applicable payment system for nonexcepted items and services furnished and billed by nonexcepted off-campus PBDs. In addition, we indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65. For a detailed discussion of the history and statutory authority related to payments under section 603 of Public Law 114–74, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729).

b. Expansion of Services at an Off-Campus PBD Excepted Under Section 1833(t)(21)(B)(ii) of the Act

In the CY 2017 OPPS/ASC proposed rule (81 FR 45685), we noted that we had received questions from some hospitals regarding whether an excepted off-campus PBD could expand the number or type of services the department furnishes and maintain excepted status for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act. We indicated that we were concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and expand services furnished by existing excepted off-campus PBDs as a result (81 FR 45685). This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believed these amendments to section 1833(t) of the Act were intended to address (81 FR 45685). We believed section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of the Bipartisan Budget Act of 2015, as guided by our regulatory definition at § 413.65(a)(2) of a department of a provider (81 FR 45685). Thus, in the CY 2017 OPPS/ASC proposed rule, we proposed that if an excepted off-campus PBD furnished items and services from a clinical family of services (clinical families of services were identified in Table 21 of the CY 2017 proposed rule (81 FR 45685 through 45686) that it did not furnish prior to November 2, 2015, and thus did not also bill for, services from these new expanded clinical families of services would not be covered OPD services, and instead would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act, as described in section X.A.1.c. of the CY 2017 proposed rule. In addition, in that rule, we proposed not to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish (81 FR 45685).

The majority of commenters, including several hospital associations, regional health systems, and medical equipment manufacturers opposed the proposal primarily because they believed: (1) CMS exceeded its statutory authority, as the statutory language included in section 603 does not address changes in service mix by excepted off-campus PBDs; (2) CMS' proposal did not account for evolving technologies and would hinder beneficiary access to those innovative technologies; (3) the term ''clinical families of service'' appeared to be a new term created by CMS for the purpose of implementing section 603 and it would be difficult for CMS and hospitals to manage changes in the composition of APCs and HCPCS code changes contained in those APCs; and (4) the proposal created significant operational challenges and administrative burden for both CMS and hospitals because commenters believed it was unnecessarily complex (81 FR 79706 through 79707).

In addition, MedPAC explained in its comment letter that the proposal was unnecessarily complex and instead suggested that CMS adopt a different approach by determining how much the Medicare program had paid an excepted off-campus PBD for services billed under the OPPS during a 12-month baseline period that preceded November 2, 2015 and to cap the OPPS payment made to the off-campus PBD at the amount paid during the baseline period.[81] Some commenters, including physician group stakeholders, supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from expanding the excepted services for which it is paid under the OPPS into wholly new clinical areas, as they believed an excepted, off-campus PBD should only be able to bill under the OPPS for those items and services for which it submitted claims prior to November 2, 2015 (82 FR 33647).

In response to public comments, we did not finalize our proposal to limit the expansion of excepted services at excepted off-campus PBDs. However, we stated our intent to monitor this issue and expressed interest in additional feedback to help us consider whether excepted off-campus PBDs that expand the types of services offered after November 2, 2015 should be paid for furnishing those items and services under the applicable payment system (that is, the PFS) instead of the OPPS. Specifically, we requested comments on how either a limitation on volume or a limitation on lines of service would work in practice (81 FR 79707).

In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79707), we sought public comments on how either a limitation on volume of services, or a limitation on lines of

[81] Available at: *http://medpac.gov/docs/default-source/comment-letters/08172016_opps_asc_comment_2017_medpac_sec.pdf?sfvrsn=0.*

service, as we laid out in the CY 2017 OPPS/ASC proposed rule, could be implemented. Specifically, we stated that we were interested in what data were available or could be collected that would have allowed us to implement a limitation on the expansion of excepted services.

We provided a summary of and responses to comments received in response to the CY 2017 OPPS/ASC final rule with comment period in the CY 2018 OPPS/ASC proposed rule. As stated in that rule, several of the public comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were repeated from the same stakeholders in response to the CY 2017 OPPS/ASC proposed rule. These commenters again expressed concern regarding CMS' authority to address changes in service-mix; that a limitation on service expansion or volume would stifle innovative care delivery and use of new technologies; and that limiting service line expansion using clinical families of service was not workable. Because these commenters did not provide new information, we referred readers to the CY 2017 OPPS/ASC final rule with comment period for our responses to comments on statutory authority and concerns about hindering access to innovative technologies (81 FR 79707 and 82 FR 59388). A summary of and our responses to the other comments received in response to the comment solicitation included in the CY 2017 OPPS/ASC final rule with comment period were included in the CY 2018 OPPS/ASC proposed rule (82 FR 33645 through 33648).

In the CY 2018 OPPS/ASC proposed rule, we did not propose any policies related to clinical service line expansion or volume increases at excepted off-campus PBDs. However, we stated that we would continue to monitor claims data for changes in billing patterns and utilization, and we again invited public comments on the issue of service line expansion. In response to the CY 2018 comment solicitation, MedPAC largely reiterated the comments it submitted in response to the CY 2017 OPPS/ASC rulemaking and acknowledged the challenges of implementing its recommended approach as such approach would necessitate CMS requiring hospitals to report the amount of OPPS payments received by each excepted off-campus PBD during the baseline period (such as November 2014 through November 2015) because CMS was not collecting data on payments made to each individual PBD during that period. In its comments, MedPAC recommended that, to help ensure the accuracy of these data, CMS could selectively audit hospitals.[82] Another commenter expressed support for CMS' efforts to continue to implement and expand site-neutral payment policies for services where payment differentials are not warranted, such as between HOPDs and ASCs or physician offices.

2. CY 2019 Proposal and Final Policy

As we previously expressed in CYs 2017 and 2018 OPPS/ASC rulemaking, we continue to be concerned that if excepted off-campus PBDs may furnish new types of services that were not provided at the excepted off-campus PBDs prior to the date of enactment of the Bipartisan Budget Act of 2015 and can be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe the section 603 amendments to section 1833(t) of the Act are intended to prevent. Of note, these statutory amendments ''came after years of nonpartisan economists, health policy experts, and providers expressing concern over the Medicare program's [OPPS] paying more for the same services provided at HOPDs than in other settings—such as an ambulatory surgery center, physician office, or community outpatient facility.'' [83] Experts raised concerns that this payment inequity drove the acquisition of ''standalone or independent practices and facilities by hospitals, resulted in higher costs for the Medicare system and taxpayers, and also resulted in beneficiaries needlessly facing higher cost-sharing in some settings than in others.'' [84] In addition, some experts argued that, ''to the extent this payment differential accelerated consolidation of providers, this would result in reduced competition among both hospitals and nonaffiliated outpatient service providers. This, in turn, could reduce large hospital systems' incentives to reduce costs, increase efficiency, or focus on patient outcomes.'' [85]

The Government Accountability Office (GAO) stated in its December 2015 Report to the Congress that ''from 2007 through 2013, the number of vertically consolidated physicians nearly doubled, with faster growth in more recent years.'' GAO concluded that, ''regardless of what has driven hospitals and physicians to vertically consolidate, paying substantially more for the same service when performed in an HOPD rather than a physician office provides an incentive to shift services that were once performed in physician offices to HOPDs after consolidations have occurred.'' [86]

While there is no Congressional Record available for section 603 of the Bipartisan Budget Act of 2015, we do not believe that Congress intended to allow for new service lines to be paid OPPS rates because providing for such payment would allow for excepted off-campus PBDs to be paid higher rates for types of services they were not furnishing prior to the date of enactment of the Bipartisan Budget Act of 2015 and that would be paid at lower rates if performed in a nonexcepted off-campus PBD. Similarly, we are concerned that a potential shift of services from nonexcepted off-campus PBDs to excepted off-campus PBDs may be occurring, given the higher payment rate in this setting. We believe that the growth of service lines in currently excepted off-campus PBDs may be an unintended consequence of our current policy, which allows continued full OPPS payment for any services furnished by excepted off-campus PBDs, including services in new service lines.

In prior rulemaking, and as discussed in section X.A. of the CY 2019 OPPS/ASC proposed rule, we noted our concerns and discussed our efforts to begin collecting data and monitoring billing patterns for off-campus PBDs. Specifically, as described in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66910 through 66914), we created HCPCS modifier ''PO'' (Services, procedures, and/or surgeries furnished at off-campus provider-based outpatient departments) for hospital claims to be reported with every code for outpatient hospital items and services furnished in an off-campus PBD of a hospital. Reporting of this new modifier was voluntary for CY 2015, with reporting required beginning on January 1, 2016. In addition, we established modifier ''PN'' (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital) to identify and pay nonexcepted items and services billed on an institutional claim.

[82] Available at: *http://medpac.gov/docs/default-source/comment-letters/09082017_opps_asc_2018_medpac_comment_sec.pdf?sfvrsn=0.*

[83] Available at: *https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/20160205SiteNeutralLetter%5b1%5d.pdf.*

[84] Ibid.

[85] Ibid.

[86] GA0–16–189, ''Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform.'' Available at: *https://www.gao.gov/assets/680/674347.pdf.*

Effective January 1, 2017, nonexcepted off-campus PBDs of a hospital were required to report this modifier on each claim line for nonexcepted items and services to trigger payment under the PFS instead of the OPPS. As a conforming revision, effective January 1, 2017, the modifier ''PO'' descriptor was revised to ''excepted service provided at an off-campus, outpatient, provider-based department of a hospital'' and this modifier continued to be used to identify items and services furnished by an excepted off-campus PBD of a hospital.

As discussed in the CY 2018 OPPS/ASC proposed rule (82 FR 33647), a few commenters supported CMS' intent to monitor service line expansion and changes in billing patterns by excepted off-campus PBDs. These commenters urged CMS to work to operationalize a method that would preclude an excepted off-campus PBD from increasing its payment advantage under the OPPS by expanding into wholly new clinical areas (82 FR 33647). Moreover, a few commenters urged CMS to pursue a limitation on service line expansion to ensure designation as an excepted off-campus PBD is not ''abused'' (82 FR 33647). One commenter suggested that CMS evaluate outpatient claims with the ''PO'' modifier to develop a list of ''grandfathered'' items and services for which the excepted off-campus PBD may continue to be paid under the OPPS (82 FR 33647). In response to these comments, we stated that we were concerned with the practicality of developing a list of excepted items and services for each excepted off-campus PBD, given the magnitude of such a list (82 FR 33647). We noted in the CY 2018 OPPS/ASC final rule with comment period, however, that we continued to monitor claims data for changes in billing patterns and utilization, and invited comments on this issue (82 FR 59388).

In light of our prior stated concerns about the expansion of services in excepted off-campus PBDs, in the CY 2019 OPPS/ASC proposed rule (83 FR 37148 through 37149), for CY 2019 and subsequent years, we proposed that if an excepted off-campus PBD furnishes services from any clinical family of services (as clinical families of services are defined in Table 32 of that proposed rule) from which it did not furnish an item or service during a baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill under the OPPS for that item or service), items and services from these new clinical families of services would not be excepted items and services and, thus, would not be covered OPD services. Instead, they would be subject to paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act and paid under the PFS. Furthermore, in the CY 2019 OPPS/ASC proposed rule, we proposed to revise 42 CFR 419.48 to limit the definition of ''excepted items and services'' in accordance with this proposal. Generally, excepted items and services are items or services that are furnished on or after January 1, 2017 by an excepted off-campus PBD (as defined in § 419.48) that has not impermissibly relocated or changed ownership. Under this proposal, beginning on January 1, 2019, excepted items and services would be items or services that are furnished and billed by an excepted off-campus PBD (defined in § 419.48) only from the clinical families of services (described later in this section) for which the excepted off-campus PBD furnished (and subsequently billed under the OPPS) for at least one item or service from November 1, 2014 through November 1, 2015. Further, for purposes of this section, ''new clinical families of services'' would be items or services: (1) That are furnished and billed by an excepted off-campus PBD; (2) that are otherwise paid under the OPPS through one of the APCs included in Table 32 of the CY 2019 OPPS/ASC proposed rule; and (3) that belong to a clinical family listed in Table 32 of the proposed rule from which the excepted off-campus PBD did not furnish an item or service during the baseline period from November 1, 2014 through November 1, 2015 (and subsequently bill for that service under the OPPS). In addition, for CY 2019, we proposed that if an excepted off-campus PBD furnishes a new item or service from a clinical family of services listed in Table 32 of the proposed rule from which the off-campus PBD furnished a service from November 1, 2014 through November 1, 2015, such service would continue to be paid under the OPPS because items and services from within a clinical family of services for which the excepted off-campus PBD furnished an item or service during the baseline period would not be considered a ''service expansion.''

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37149), in order to determine the types of services provided at an excepted off-campus PBD, for purposes of OPPS payment eligibility, excepted off-campus PBDs would be required to ascertain the clinical families from which they furnished services from November 1, 2014 through November 1, 2015 (that were subsequently billed under the OPPS). In addition, items and services furnished by an excepted off-campus PBD that were not identified in Table 32 of the proposed rule would be reported with modifier ''PN''. We selected the year prior to the date of enactment of the Bipartisan Budget Act of 2015 as the baseline period because it is the most recent year preceding the date of enactment of section 603 and we believed that a full year of claims data would adequately reflect the types of service lines furnished and billed by an excepted off-campus PBD. We considered expanding the baseline period to include a timeframe prior to November 2014, but did not propose this alternative due to the possibility that hospital claims data for an earlier time period might not be readily available and reviewing claims from a longer timeframe may impose undue burden. If an excepted off-campus PBD did not furnish services under the OPPS until after November 1, 2014, we proposed that the 1-year baseline period begins on the first date the off-campus PBD furnished covered OPD services prior to November 2, 2015. For providers that met the mid-build requirement (as defined at section 1833(t)(21)(B)(v) of the Act), we proposed to establish a 1-year baseline period that begins on the first date the off-campus PBDs furnished a service billed under the OPPS. We proposed changes to our regulation at 42 CFR 419.48 to include these alternative baseline periods. For guidance on the implementation of sections 16001 and 16002 of the 21st Century Cures Act, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Sections-16001-16002.pdf*. We stated in the proposed rule that we were concerned that a 1-year baseline may be unnecessarily long to the extent that such baseline would be, at least in part, a prospective period during which such departments would have time and an incentive to bill services from as many service lines as possible, thereby limiting the effect of this policy. We welcomed public comment on whether a different baseline period, such as 3 or 6 months, should be used for off-campus PBDs that began furnishing services and billing after November 1, 2014, or that met the mid-build requirement.

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37149), we were aware of past stakeholder concern regarding limiting service line expansion for excepted off-campus PBDs using the 19 clinical families identified in Table 32 of the proposed

rule. However, we believed that the proposed clinical families recognized all clinically distinct service lines for which a PBD might bill under the OPPS, while at the same time allowing for new services within a clinical family of services to be considered for designation as ''excepted items and services'', as defined in the regulations at 42 CFR 419.48 where the types of services within a clinical family expand due to new technology or innovation. We stated in the proposed rule that we believed that requiring excepted off-campus PBDs to limit their services to the exact same services they furnished during the proposed baseline period would be too restrictive and administratively burdensome. We requested public comments on the proposed clinical families. We also solicited public comments on whether any specific groups of hospitals should be excluded from our proposal to limit the expansion of excepted services, such as certain rural hospitals (for example, rural sole community hospitals), in light of recent reports of hospital closures in rural areas.

In addition, we solicited public comments on alternate methodologies to limit the expansion of excepted services in excepted off-campus PBDs for CY 2019. Specifically, we invited public comments on the adoption and implementation of other methodologies, such as the approach recommended by MedPAC (discussed earlier in this section) in response to the CY 2017 and CY 2018 proposals whereby CMS would establish a baseline service volume for each applicable off-campus PBD, cap excepted services (regardless of clinical family) at that limit, and when the hospital reaches the annual cap for that location, additional services furnished by that off-campus PBD would no longer be considered covered OPD services and would instead be paid under the PFS (the annual cap could be updated based on the annual updates to the OPPS payment rates). Under such alternate approach, hospitals would need to report service volume for each off-campus PBD for the applicable period (such as November 1, 2014–November 1, 2015) and such applicable periods would be subject to audit.

Comment: Some commenters, including an organization representing orthopaedic surgeons, commended CMS for its efforts to expand the application of site neutral payments to additional items and services in excepted off-campus PBDs. These commenters asserted that the expansion of services in excepted off-campus PBDs has an adverse effect on the control of unnecessary utilization of services in PBDs. One commenter who supported the proposal stated that ''all sites of service should provide the same service at the same cost'' and that Medicare ''should not be in the business of supporting or favoring more expensive sites of service, when the service can be furnished safely at a less expensive'' and more efficient setting. Another commenter argued that the consolidation of these facilities effectively inhibits a physician's ability to refer freely to the best specialists or most affordable health centers, and obstructs patients' access to potentially better, more affordable care without their knowledge.

One commenter, a pharmaceutical research and manufacturing organization, stated that this proposal ''strikes a reasonable balance'' in that the proposal would not limit PBDs to exactly the same services that they provided in the past, but would allow them to adjust their service-mix within relevant clinical families that reflect their specialties. The commenter contended that this provision would permit appropriate changes to the services excepted off-campus PBDs offer as clinical practices evolve. Additionally, the commenter stated that this policy proposal would prevent attempts to circumvent ''the obvious intent of the law to reign in conversion of non-hospital entities into PBDs primarily in order to secure better payment, but without commensurate clinical benefit.''

A few commenters stated that most off-campus PBDs are able to take advantage of higher payment rates for a wide variety of services. Specifically, the commenters asserted that, given the significant payment disparities for certain services (for example, based on OPPS rates versus PFS rates—chemotherapy: $281 versus $136; cardiac imaging: $2,078 versus $655; and colonoscopy: $1,383 versus $625), hospital systems have been purchasing physician practices and, by integrating them with excepted off-campus PBDs, secured OPPS payment rates for these services.

Another commenter asserted that CMS is taking important steps to close loopholes that have enabled hospitals to continue driving volume of services through excepted off-campus PBDs. Moreover, the commenter noted that the current policy has caused ''hundreds of hospitals that have already absorbed physician practices and converted them into PBDs . . . to enjoy an unfair reimbursement advantage'' over other providers. The commenter further asserted that the proposal does not sufficiently limit the items and services for which an excepted off-campus PBD can seek payment under the OPPS, and that the proposal would still allow a PBD to expand its services ''no matter how limited the PBD's range or volume of services were within that clinical family'' during the baseline period. The commenter also expressed concern that CMS did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD can furnish, and indicated that, without such limitation, an excepted off-campus PBD has every incentive to grow the scope of its practice in order to maximize its ability to seek payment under the OPPS. Moreover, this commenter contended that CMS could require that ''excepted'' status be tied to those physicians and particular services that were in place at the off-campus PBD prior to November 2, 2015. In other words, an excepted off-campus PBD would not be able to seek payment under the OPPS with respect to: (1) Items or services furnished by a physician (as identified by National Provider Identifier) who did not furnish items or services at the off-campus PBD prior to November 2, 2015; or (2) any items or services that were not among the items or services for which the off-campus PBD billed Medicare at any point in the 12 months preceding November 2, 2015.

Accordingly, the commenter urged CMS to modify the portion of the proposed rule that would enable excepted PBDs to bill under the OPPS for any and all items and services within the clinical families through which the excepted PBDs had furnished care during the 12 months prior to November 2, 2015, and to adopt, instead, a policy that would limit excepted off-campus PBDs to billing under the OPPS for those items and services furnished in a hospital's outpatient department in the year prior to November 2, 2015, and within the specific, excepted PBD in 2016.

Response: We thank the commenters for their support and for the many detailed comments on this topic. As mentioned in the proposed rule, we are concerned that if excepted off-campus PBDs can expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs. This could result in newly purchased physician practices furnishing services that are paid at OPPS rates, which we believe the

amendments to section 1833(t) of the Act are intended to prevent.

However, while we continue to believe that section 1833(t)(21)(B)(ii) of the Act excepted off-campus PBDs as they existed at the time that Pub. L. 114–74 was enacted, and provides the authority to define excepted off-campus PBDs, including those items and services furnished and billed by such a PBD that may be paid under the OPPS, we are concerned that the implementation of this payment policy may pose operational challenges and administrative burden for both CMS and hospitals. After consideration of the public comments we received, we are not finalizing this policy as detailed below.

Comment: A few commenters suggested that CMS revise the proposed clinical families to modify the proposed 19 clinical APC groups and services. We will continue to study issues related to the expansion of services at excepted off-campus PBDs and take these comments into consideration for future rulemaking.

Response: We appreciate the feedback we received from the commenters.

Comment: One commenter asserted that the proposed 12-month baseline period was not ''necessary,'' and suggested that a 6-month baseline period would adequately capture any service line initially intended for provision at a PBD. However, another commenter suggested that CMS extend the baseline period to 3 years prior to the enactment of the BBA of 2015, to ensure that all items and services provided by an excepted off-campus PBD prior to November 2, 2015 would be excepted from the proposed payment policy.

Response: We thank the commenters for their feedback. We are not finalizing our proposed policy at this time. We intend to monitor the expansion of services in excepted off-campus PBDs. We may propose to adopt a limitation on the expansion of services in future rulemaking and will take this comment into consideration.

Comment: The majority of commenters, including individual stakeholders and hospital systems and associations, opposed the proposal to limit the expansion of services in excepted off-campus PBDs. The commonly cited concerns among the commenters who opposed the proposed policy were as follows:

Many commenters stated that the proposal is arbitrary and capricious, that CMS lacks statutory authority to pay new clinical families of service in excepted off-campus PBDs at the rate paid to nonexcepted PBDs, and that the proposal would pose operational challenges and create administrative burden on hospitals. In addition, some commenters asserted that the requirements for provider-based status are designed to ''ensure integration with the main hospital'' and, accordingly, these facilities should be able to ''furnish health care services of the same type as the main provider.''

MedPAC expressed concern that CMS' proposed approach to address the issue of undesirable incentives for excepted PBDs was unnecessarily complex. MedPAC believed that a better approach would be for CMS to determine how much the Medicare program had paid an off-campus PBD for items and services billed under the OPPS during a 12-month baseline period, specifically, CY 2017. Then, beginning January 1, 2019, annual program spending for items and services billed by the PBD under the OPPS would be capped at the amount paid to the PBD during the baseline period. However, MedPAC acknowledged that, for hospitals that have more than one excepted off-campus PBD, CMS would have to determine which claims to attribute to each excepted off-campus PBD. MedPAC believed that this approach would be easier to administer and would curb the ability of hospitals to benefit financially from purchasing freestanding physician practices and converting them to off-campus PBDs.

Several commenters argued that off-campus PBDs must be able to expand the items and services that they offer in order to meet changes in clinical practice and the changing needs of their communities without losing their ability to be paid under the OPPS. Generally, these commenters asserted that finalizing this proposal would significantly discourage hospitals from offering new and enhanced outpatient services and, as a result, the payment policy would hinder beneficiary access to innovative technologies.

Many commenters asserted that it is unclear how CMS or hospitals will determine what service families were being provided during the baseline period, given the lack of department-specific data and that provider-based attestations are voluntary. In addition, these commenters contended that, even if CMS and the providers could identify the clinical families of services furnished during the baseline period, it would be exceedingly complicated and burdensome to providers and CMS to ensure services belonging to a new clinical family for the PBD are accurately reported.

Response: We appreciate the detailed comments that were submitted, and we recognize that services provided in off-campus PBDs may evolve to reflect changes in clinical practice and community health care needs. As discussed in the CY 2017 OPPS/ASC proposed rule and final rule with comment period (81 FR 45685 through 45686 and 81 FR 79706 through 79707), we believe section 1833(t)(21)(B)(ii) of the Act, as added by section 603 of Public Law 114–74, excepts off-campus provider-based departments and the items and services that are furnished by such excepted off-campus PBDs for purposes of paragraphs (1)(B)(v) and (21) of section 1833(t) of the Act as they were being furnished on the date of enactment of section 603 of Public Law 114–74, as guided by our regulatory definition of a department of a provider at § 413.65(a)(2). We also believe that we have the authority to define excepted items and services furnished and billed by excepted off-campus PBDs that may be paid under the OPPS. While we disagree with the commenters' assertion that section 603 does not provide us the authority to adopt a policy that would limit OPPS payment to the type of services that had been furnished and billed at an off-campus PBD prior to enactment of Public Law 114–74, we are concerned that the implementation of this payment policy may be operationally complex and could create an administrative burden for hospitals.

We believe the statute gives us the authority to limit the volume of services furnished to the level that was furnished prior to the date of enactment; however, we did not propose to do so. As we mentioned in the proposed rule and reiterated earlier in this section, we are concerned that if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs.

Several commenters, including MedPAC, asserted that our proposed policy could be operationally complex and could create an administrative burden for hospitals, CMS, and CMS contractors to identify, track, and monitor billing for clinical services. We agree with these commenters regarding these concerns. Therefore, we are not finalizing our proposed policy.

Comment: Some commenters, specifically hospital associations that opposed the proposal, asserted that CMS did not provide any claims-based or other supporting evidence that demonstrates that excepted off-campus PBDs are taking advantage of the current

policy. Further, these commenters noted that many of the services listed in the detailed families of services are not payable in a physician office setting and can only be provided in a hospital setting. In addition, some of these commenters urged CMS to exempt rural sole community hospitals and other vulnerable facilities from the policy proposal.

Response: We appreciate the commenters' detailed responses to our proposal. We are collecting data on the claims billed by off-campus PBDs with modifier ''PO'' (for excepted services) and modifier ''PN'' (for nonexcepted services). We believe that data collected using these modifiers will be a useful tool in furthering our efforts to monitor the expansion of services at excepted off-campus PBDs and to address any issues as they may arise. We will continue to monitor claims data for changes in billing patterns and utilization and investigate methods to ensure all hospitals are treated as fairly as possible within the program.

After consideration of the public comments we received, we are not finalizing this proposal at this time. However, we intend to monitor expansion of services in off-campus PBDs and, if appropriate, may propose to adopt a limitation on the expansion of excepted services in future rulemaking. In that event, we will consider the concerns expressed by commenters on the proposed policy in development of any future rulemaking on service line expansion. Therefore, an excepted off-campus PBD will continue to receive payments under the OPPS in CY 2019 for all billed items and services that are paid under the OPPS, regardless of whether it furnished such items and services prior to the date of enactment of Public Law 114–74, as long as the excepted off-campus PBD remains excepted, including meeting the relocation and change of ownership requirements adopted in the CY 2017 OPPS/ASC final rule with comment period if applicable (81 FR 79705 through 79706 and 79708 through 79709). As mentioned earlier in this section, we intend to monitor this issue and continue to consider how potential policies could address this issue.

XI. CY 2019 OPPS Payment Status and Comment Indicators

A. CY 2019 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also, whether particular OPPS policies apply to the code.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37150), for CY 2019, we did not propose to make any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2018 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.*

Comment: One commenter recommended that CMS split status indicator ''C'' into ''C1'' and ''C2'' in the interest of improved clarity and transparency. The commenter noted this methodology is very similar to the way Medicare split status indicator ''E'' into indicators ''E1'' and ''E2.'' The commenter requested that CMS identify inpatient only (IPO) procedures that are on the separate procedure list (as determined by the American Medical Association) with a unique status indicator such as ''C1'' and others as ''C2''. The commenter believed that the presence of a unique status indicator would ultimately assist providers in ensuring that their claims processing system edits are set up to bill these scenarios on an OPPS claim to CMS, and that CMS would benefit by having more accurate claims data submitted. The commenter believed that this will also increase the number of claims available for capturing cost data and utilizing for future ratesetting.

The commenter also requested that CMS reiterate that the I/OCE logic regarding IPO procedures that are classified as a separate procedure (for example, status indicator of ''C1'') is a line item rejection and does not cause the entire claim to be rejected.

Response: We appreciate the commenter's concerns. However, at this time, we do not believe it is necessary to establish a unique status indicator to identify IPO procedures that are on the separate procedures list. As stated in the latest October 2018 Integrated (IOCE) CMS Specifications V19.3 document, these procedures are bypassed when performed incidental to a surgical procedure with status indicator ''T'', or effective January 1, 2015, if reported on a claim with a comprehensive APC procedure (status indicator = ''J1''). The line(s) with the inpatient-separate procedure is/are rejected by the I/OCE with Edit 45 ''Inpatient separate procedures not paid'' and the claim is processed per usual OPPS rules. Therefore, there is no need to split the definition of status indicator ''C'' and to establish a new status indicator ''C1'' as suggested by the commenter. As discussed previously, our status indicators exist for purposes of assisting in determining payment, and a single status indicator ''C'' is sufficient for services that CMS designates to be ''inpatient only'' services, regardless of whether or not they are on the separate procedure list.

There are currently 26 different status indicators in Addendum D1 that are used to indicate whether a service described by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS payment policies apply to the code. We believe that it is important to maintain only status indicators in the OPPS that convey the necessary payment-related information, and that additional indicators should only be created when necessary for payment policy purposes.

In regard to the comment related to the I/OCE, the latest October 2018 I/OCE CMS Specifications V19.3 document on the CMS website located at: *https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs.html* already contains the correct logic regarding IPO procedures that are classified as a separate procedures.

After considering the comments received, we continue to believe that the existing definitions of the OPPS status indicators will be appropriate for CY 2019. Therefore, we are finalizing our proposed policy without modifications.

The complete list of the payment status indicators and their definitions that will apply for CY 2019 is displayed in Addendum D1 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The CY 2019 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

B. CY 2019 Comment Indicator Definitions

In the CY 2019 OPPS/ASC proposed rule (83 FR 37150), we proposed to use four comment indicators for the CY 2019 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2018 and we proposed to continue their use in CY 2019. The

proposed CY 2019 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

We did not receive any public comments regarding the proposed CY 2019 OPPS comment indicators. Therefore, we are adopting, as final, our proposal to continue to use for CY 2019 comment indicators ''CH'', ''NI'', ''NP'', and ''NP''. The definitions of the final OPPS comment indicators for CY 2019 are listed in Addendum D2 to this final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

XII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, 2017 and 2018 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; and 82 FR 59401 through 59424, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the AMA and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process, which we finalized in the CY 2012 OPPS/ASC final rule with comment period, is used to update HCPCS and CPT codes (76 FR 42291; 76 FR 74380 through 74381).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures (including all procedures newly proposed for removal from the OPPS

inpatient list), new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPPS (72 FR 42478).

As we noted in the CY 2008 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures (72 FR 42477).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we noted that some stakeholders have suggested that certain procedures that are outside the CPT surgical range but that are similar to surgical procedures currently covered in an ASC setting should be ASC covered surgical procedures. For example, some stakeholders have recommended adding certain cardiovascular procedures to the ASC Covered Procedures List (CPL) due to their similarity to currently covered peripheral endovascular procedures in the surgical code range for surgery and the cardiovascular system. Further, stakeholders also noted that the AMA's CPT code manual states that the listing of a procedure in a specific section of the book may reflect historical or other considerations and should not be interpreted as strictly classifying the procedure as ''surgery'' or ''not surgery'' for insurance purposes. As the CPT codebook states: ''It is equally important to recognize that as techniques in medicine and surgery have evolved, new types of services, including minimally invasive surgery, as well as endovascular, percutaneous, and endoscopic interventions have challenged the traditional distinction of Surgery vs Medicine. *Thus, the listing of a service or procedure in a specific section of this book should not be interpreted as strictly classifying the service or procedure as 'surgery' or 'not surgery' for insurance or other purposes.* The placement of a given service in a specific section of the book may reflect historical or other considerations (*e.g.,* placement of the percutaneous peripheral vascular endovascular interventions in the Surgery/Cardiovascular System section, while the percutaneous coronary interventions appear in the Medicine/Cardiovascular section)'' (emphasis added) (CPT® 2018 Professional Edition, ''Instructions for Use of the CPT Code Book,'' page xii.). While we continue to believe that using the CPT code range to define surgery represents a logical, appropriate, and straightforward approach to defining a surgical procedure, we also believe it may be appropriate for us to use the CPT surgical range as a guide rather than a strict determinant as to whether a procedure is surgical, which would give us more flexibility to include ''surgery-like'' procedures on the ASC CPL.

We also are cognizant of the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59402 through 59403), we responded to public comments that we had solicited regarding services that are described by Category I CPT codes outside of the surgical range, or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures that are payable when furnished in the ASC setting. Commenters offered mixed views of changing the current definition of surgery; however, most commenters were supportive of changing the definition. Some commenters recommended broadening the definition of surgery to include procedures not described by the CPT surgical range. Another commenter recommended making all surgical codes payable in a hospital outpatient department payable in an ASC and further suggested that CMS at least redefine surgical procedures to include invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization.

One commenter recommended using a definition of surgery developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values. In calculating the professional liability insurance relative values, certain cardiology codes outside the CPT surgical range are considered surgical codes for both the calculation and assignment of the surgery-specific malpractice risk factors. However, we note that the distinction between ''surgical'' and ''nonsurgical'' codes developed by the AMA Specialty Society Relative Value Scale Update Society is used by CMS to calculate professional liability risk factors and not necessarily to define surgery. The codes considered surgeries by the AMA Society Relative Value Scale Update Society were most recently displayed on the CMS website for the CY 2018 Medicare Physician Fee Schedule final rule under the file ''Invasive Cardiology Services Outside of Surgical HCPCS Code Range Considered Surgery.'' We refer readers to that file, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2018-PFS-FR-Invasive-Cardiology.zip.*

In the CY 2019 OPPS/ASC proposed rule (83 FR 37152), after further consideration of comments we received in response to the CY 2018 OPPS/ASC final rule with comment period, we proposed to revise our definition of ''surgery'' for CY 2019 to account for ''surgery-like'' procedures that are assigned codes outside the CPT surgical range (10000 through 69999). We

believe it is appropriate to expand our definition of covered surgical procedures to include Category I CPT codes that are not in the Category I CPT surgical range but that directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range because, as commenters have noted, the CPT Codebook's classification of certain procedures as ''surgical'' should not be considered dispositive of whether a procedure is or is not surgery. We also believe that considering these codes for potential inclusion on the covered surgical procedures list is consistent with our policy for Level II HCPCS codes and Category III CPT codes.

For CY 2019, we proposed that these newly eligible ''surgery-like'' procedures are procedures that are described by Category I CPT codes that are not in the surgical range but, like procedures described by Level II HCPCS codes or by Category III CPT codes under our current policy, directly crosswalk or are clinically similar to procedures in the Category I CPT surgical range. These Category I CPT codes would be limited to those that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

We invited comments on our proposal to revise the definition of surgery for the ASC prospective payment system. We also solicited comments on whether we should expand our definition of ''surgery'' to include procedures that fall outside the CPT surgical range, but fall within the definition of ''surgery'' developed by the AMA Specialty Society Relative Value Scale Update Society for use in the agency's Physician Fee Schedule (PFS) professional liability insurance relative values, that we determine do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

Comment: A majority of commenters supported the proposal, stating that the expansion of the definition of surgery would allow Medicare beneficiaries access to these procedures at a safe, lower-priced and more convenient site of service. One commenter expressed general concern about the proposal to revise the definition of surgery, citing ''surgery-like'' procedures that might expose Medicare beneficiaries to a significant safety risk when performed in an ASC.

Response: We appreciate commenters' support. As we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37152), we are cognizant of the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade. We also noted that the AMA's CPT code manual states that the listing of a procedure in a specific section of the book may reflect historical or other considerations and should not be interpreted as strictly classifying the procedure as ''surgery'' or ''not surgery'' for insurance or other purposes.

With respect to the commenter's concern that this proposal may expose beneficiaries to significant safety risk, we note that any procedure added to the ASC CPL is evaluated against the existing regulatory criteria and would not be expected pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and is separately paid under the OPPS. In addition, we expect that physicians treating beneficiaries are well-equipped to decide whether the ASC setting would be appropriate based on the clinical needs of the patient, among other factors. Therefore, we do not share the commenter's concern.

Comment: One commenter asked CMS to clarify if it bases its determination of whether a procedure is an ASC covered surgical procedure on the fact that the procedure does not require an ''overnight'' stay or the fact that the procedure requires less than 24 hours of active medical care following the procedure.

Response: As codified in our regulations at 42 CFR 416.166(b), covered surgical procedures are surgical procedures for which, among other things, standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. In the CY 2019 OPPS/ASC proposed rule (83 FR 37151), we explained this requirement by stating that we would not expect a covered surgical procedure to require an overnight stay when performed in the ASC. Also in the CY 2019 OPPS/ASC proposed rule, we explained that we adopted this standard for defining which surgical procedures are covered surgical procedures under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs (83 FR 37151). We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate for Medicare beneficiaries in ASCs.

After consideration of the public comments we received, we are finalizing our proposal to define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the American Medical Association (AMA) defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised Category I and Category III CPT Codes and Level II HCPCS Codes

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code

descriptors that necessitate a change in the current ASC payment indicator. To clarify, we referred to these codes as new and revised in the CY 2018 OPPS/ASC proposed rule.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37152 through 37155), we separated our discussion based on when the codes were released and whether we were soliciting public comments in the proposed rule (and responding to those comments in this CY 2019 OPPS/ASC final rule with comment period) or whether we would be soliciting public comments in this CY 2019 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2020 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59405 through 59406) on the new and revised Level II HCPCS codes effective October 1, 2017 or January 1, 2018. These new and revised codes, with an effective date of October 1, 2017 or January 1, 2018, were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2018 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2018 OPPS/ASC final rule with comment period. In the CY 2019 OPPS/ASC proposed rule, we stated that we will respond to public comments and finalize the treatment of these codes under the ASC payment system in this CY 2019 OPPS/ASC final rule with comment period.

As we did in Table 33 of the CY 2019 OPPS/ASC proposed rule (83 FR 37153), in Table 52 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the OPPS.

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TABLE 52.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW OR REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2018	Level II HCPCS Codes	April 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
July 1, 2018	Level II HCPCS Codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2018	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
October 1, 2018	Level II HCPCS Codes	October 1, 2018	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period
January 1, 2019	Category I and III CPT Codes	January 1, 2019	CY 2019 OPPS/ASC proposed rule	CY 2019 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2019	CY 2019 OPPS/ASC final rule with comment period	CY 2020 OPPS/ASC final rule with comment period

2. Treatment of New and Revised Level II HCPCS Codes Implemented in April 2018 for Which We Solicited Public Comments in the CY 2019 OPPS/ASC Proposed Rule

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37153), in the April 2018 ASC quarterly update (Transmittal 3996, Change Request 10530, dated March 09, 2018), we added nine new Level II HCPCS codes to the ASC CPL and list of covered ancillary services. Table 34 of the proposed rule (83 FR 37153) listed the new Level II HCPCS codes that were implemented April 1, 2018, along with their proposed payment indicators for CY 2019. We invited public comments on these proposed payment indicators and the proposed payment rates for the new Level II HCPCS codes that were recognized as ASC covered surgical procedures or ancillary services in April 2018 through the quarterly update CRs, as listed in Table 34 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in this CY 2019 OPPS/ASC final rule with comment period.

Comment: Several commenters supported the addition of HCPCS code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s)), which describes the Latera implant surgical procedure, to the ASC covered surgical procedures list and its designation as a device-intensive procedure. However, they expressed concern that the proposed ASC payment rate for the procedure does not sufficiently cover the full cost of providing the surgery. One commenter stated that the proposed ASC payment rate of approximately $1,271 does not cover the cost of the device implant, let alone the full cost of the procedure including the device. These commenters believed that the low payment rate would hinder physicians from offering the procedure in ASCs. The commenters requested that CMS review the payment rate and adjust it appropriately so that physicians can continue to perform this procedure safely and effectively in the ASC setting.

Response: The OPPS and the ASC payment system utilize different conversion factors to establish payment rates for covered services to account for changes in expenditures. In the CY 2019 OPPS/ASC proposed rule, we stated that the proposed OPPS conversion factor was $79.546, while the proposed ASC conversion factor was $46.500. Consequently, the proposed ASC payment rate of approximately $1,271 for HCPCS code C9749 would be less than the proposed OPPS payment rate of approximately $2,241. We have used different conversion factor updates for the OPPS and the ASC payment system since the revised ASC payment system was implemented on January 1, 2008. For more information regarding the payment methodology for ASC services, we refer readers to section XII.G. (Calculation of the ASC Payment Rates and the ASC Conversion Factor) of this CY 2019 OPPS/ASC final rule with comment period.

Further, we also note that HCPCS code C9749 has been assigned a payment indicator of ''J8'' and is therefore designated as a device-intensive procedure. As discussed in section XII.C.1.b. of this final rule with comment period, under the ASC payment system, device-intensive procedures are paid a higher payment than if the procedure was not designated as device-intensive.

After consideration of the public comments we received, we are adopting as final the CY 2019 proposed payment indicators for new level II HCPCS codes for covered surgical procedures and ancillary services effective on April 1, 2018, as indicated in Table 53. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2019. The replacement codes are listed in Table 53. The final payment rates for these codes can be found in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the payment indicator definitions can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 53.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 PI
C9462	C9462	Injection, delafloxacin, 1 mg	K2
C9463	J0185	Injection, aprepitant, 1 mg	K2
C9464	J2797	Injection, rolapitant, 0.5 mg	K2
C9465	J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg	K2
C9466	J0517	Injection, benralizumab, 1 mg	K2
C9467	J9311	lnjection, rituximab 10 mg and hyaluronidase	K2
C9468	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	K2
C9469*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
C9749	C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	J8

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018. HCPCS code Q9993 was deleted December 31, 2018, and replaced with HCPCS code J3304 effective January 1, 2019.

3. Treatment of New and Revised Category III CPT and Level II HCPCS Codes Implemented in July 2018 for Which We Solicited Public Comments in the CY 2019 OPPS/ASC Proposed Rule

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37154), in the July 2018 ASC quarterly update (Transmittal 4076, Change Request 10788, dated June 26, 2018), we added eight new Level II HCPCS codes to the list of covered ancillary services. In Table 35 of the proposed rule (83 FR 37154), we listed the new HCPCS codes that are effective July 1, 2018.

In addition, through the July 2018 quarterly update CR, we also implemented one new Category III CPT code as an ASC covered ancillary service effective July 1, 2018. This code was listed in Table 36 of the proposed rule, along with its proposed payment indicator. The proposed payment rate for this new Category III CPT code was included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

We invited public comments on these proposed payment indicators and the proposed payment rates for the new Category III CPT code and Level II HCPCS codes that were expected to be newly recognized as ASC covered surgical procedures or covered ancillary services in July 2018 through the quarterly update CRs, as listed in Tables 35 and 36 of the proposed rule. We proposed to finalize their payment indicators and their payment rates in the CY 2019 OPPS/ASC final rule with comment period.

We did not receive any public comments regarding these proposed ASC payment indicators and payment rates. Therefore, we are adopting as final the CY 2019 proposed payment indicators for these codes, as indicated in Tables 54 and 55. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2019. Their replacement codes are listed in Table 55. The final payment rates for these codes for CY 2019 can be found in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the payment indicator definitions can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 54.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2018

CY 2018 HCPCS Code	CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 PI
C9030	J9057	Injection, copanlisib, 1 mg	K2
C9032	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	K2
Q5105	Q5105	Injection, epoetin alfa, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	K2
Q5106	Q5106	Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units	K2
Q9991	Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	K2
Q9992	Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	K2
Q9993*	J3304*	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	K2
Q9995	J7170	Injection, emicizumab-kxwh, 0.5 mg	K2

*HCPCS code C9469 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg), which was effective April 1, 2018, was deleted June 30, 2018 and replaced with HCPCS code Q9993 (Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg) effective July 1, 2018. HCPCS code Q9993 was deleted December 31, 2018, and replaced with HCPCS code J3304 effective January 1, 2019.

TABLE 55.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2018

CY 2018 CPT Code	CY 2019 CPT Code	CY 2019 Long Descriptor	Final CY 2019 PI
0508T	0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Z2

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4. Process for New and Revised Level II HCPCS Codes That Will Be Effective October 1, 2018 and January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new and revised Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the OPPS and the ASC payment system for the following calendar year. These codes are released to the public via the CMS HCPCS website, and also through the January OPPS quarterly update CRs. In the past, we also released new and revised Level II HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37154), for CY 2019, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2018 and January 1, 2019 would be flagged with comment indicator ''NI'' in Addendum B to the CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2019. We did not receive any public comments on our proposal. As we stated that we would do in the proposed rule, we are inviting public comments in this CY 2019 OPPS/ASC final rule with comment period on the interim status indicator and APC assignments, and

payment rates for these codes that will be finalized in the CY 2020 OPPS/ASC final rule with comment period.

5. Process for Recognizing New and Revised Category I and Category III CPT Codes That Will Be Effective January 1, 2019 for Which We Are Soliciting Public Comments in This CY 2019 OPPS/ASC Final Rule With Comment Period

We generally include the new and revised CPT codes that are effective January 1 of a calendar year in the proposed rule to request public comments on the ASC payment indicator assignments. In addition, these codes are assigned to comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year and that comments will be accepted on the proposed payment indicator. There are no existing codes with substantial revision to the code descriptor effective January 1, 2019. However, we inadvertently omitted most of the new Category I and III CPT codes effective January 1, 2019 from ASC Addendum AA, BB, and EE to the CY 2019 OPPS/ASC proposed rule. We did not omit eight new CPT codes that we proposed to designate as temporarily office based effective January 1, 2019. We refer readers to Table 39 of the proposed rule.

Therefore, in addition to the Level II HCPCS codes that will be effective October 1, 2018, and January 1, 2019, we are flagging the new Category I and III CPT codes that will be effective January 1, 2019, that were omitted from the CY 2019 OPPS/ASC proposed rule, with comment indicator ''NI'' in ASC Addendum AA, BB, and EE to this CY 2019 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment indicator for CY 2019. We are inviting public comments on the interim ASC payment indicator assignments and payment rates for these codes that we intend to finalize in the CY 2020 OPPS/ASC final rule with comment period. We note that we are finalizing the ASC payment indicators for the eight codes that we proposed to designate as temporarily office based effective January 1, 2019 because we previously sought comments on their ASC payment indicator assignment. Table 58 of this final rule with comment period contains the list of these eight codes and their final ASC payment indicators.

Further, we remind readers that the CPT code descriptors that appear in ASC Addendum AA, BB, and EE are short descriptors and do not fully describe the complete procedure, service, or item described by the CPT code. Therefore, we have included the 5-digit CPT codes and their long descriptors for the new CPT codes in Addendum O (which is available via the internet on the CMS website) so that the public can adequately comment on our interim ASC payment indicator assignments.

In summary, we are soliciting public comments on the interim ASC payment indicators for the new Category I and III CPT codes that will be effective January 1, 2019, which we have assigned to ASC comment indicator ''NI'' in this CY 2019 OPPS/ASC final rule with comment period. We intend to finalize the interim ASC payment indicators in the CY 2020 OPPS/ASC final rule with comment period. The CPT codes are listed in ASC Addendum AA, BB, and EE with short descriptors only but we list them again in Addendum O with long descriptors.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC CPL in CY 2008 or later years that we determine are performed predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2019 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2019 OPPS/ASC proposed rule and this final rule with comment period, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. We reviewed CY 2017 volume and utilization data and the clinical characteristics for all covered surgical procedures that are assigned payment indicator ''G2'' (Nonoffice-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in CY 2017, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59406 through 59408).

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37155 through 37157), our review of the CY 2017 volume and utilization data resulted in our identification of 4 covered surgical procedures that we believe meet the criteria for designation as office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2019 were listed in Table 37 of the proposed rule (83 FR 37156).

Comment: Several commenters disagreed with the proposal to designate CPT codes 36902 (Intro cath dialysis circuit) and 36905 (Thrmbc/nfs dialysis

circuit) as permanently office-based. Commenters suggested that a permanent office-based designation, and therefore a permanent payment rate of the lesser of the PFS nonfacility PE RVU-based or the OPPS relative weight amount, would pay too little to make it a viable option for ASCs to perform these vascular access services, which the commenters suggested is the optimal setting for receiving vascular access services. Commenters also suggested that a permanent office-based designation may inadvertently incentivize the migration of vascular access procedures to the more costly hospital setting. Further, commenters noted that vascular access procedure codes (CPT codes 36901 through 36909) became effective January 1, 2017, and were added to the ASC CPL for CY 2017. Because several of these procedures were not included on the ASC CPL prior to that time, commenters expressed concern that CMS is not likely to have data that accurately reflect the ASC utilization of the full suite of vascular access procedures until CY 2020 or later.

Some commenters recommended that CMS delay the proposal to designate CPT codes 36902 and 36905 as office-based procedures. Other commenters recommended that CMS permanently exempt such CPT codes from office-based designations, similar to the existing exemptions from the policy governing payment for covered ancillary radiology services for certain nuclear medicine procedures (CPT codes 78000 through 78999) and those covered ancillary radiology services that use a contrast agent as codified under 42 CFR 416.171(d). Commenters believed that such an exemption is warranted because certain vascular access add-on procedures (that is, CPT codes 36907, 36908, and 36909) are often billed with CPT codes 36902 and 36905, which are separately payable under the PFS but are packaged under the OPPS and the ASC payment system. Therefore, the commenters stated, the ASC payment rate for an office-based vascular access procedure with a vascular access add-on procedure may be lower than would otherwise be paid under the PFS.

Response: We appreciate the commenters' feedback on our proposal. As noted in the proposed rule, we assign office-based designations when our data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. We believe this is the most appropriate approach to prevent creating a payment incentive to migrate lower complexity services on the ASC CPL from physicians' offices to ASCs.

In response to the comment recommending that we establish a permanent office-based designation exemption for vascular access procedures, we do not believe such an exemption is necessary at this time. However, we would like to study this issue further in future policy development. As stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), we established an exemption to the policy governing payment for covered ancillary radiology services for certain nuclear medicine procedures (CPT codes 78000 through 78999) because the PFS nonfacility PE RVU amounts did not reflect the diagnostic radiopharmaceutical costs, which are paid separately under the MPFS. In addition, as stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the PFS), we exempted radiology services that use contrast agents from our policy governing payment for covered ancillary radiology services so that payment for these procedures will be based on the OPPS relative payment weight and will, therefore, include the cost for the contrast agent. We did not propose an equivalent exception for vascular access codes for CY 2019, and do not believe permanent exemption would be appropriate at this time. However, we intend to examine whether CPT codes 36902 and 36905 may be subject to circumstances similar to those that led to the exemptions for certain nuclear medicine procedures and radiology procedures that use contrast agents in future rulemaking.

The most recent full year for which we have claims, volume, and utilization data is CY 2017. We believe these data are generally an appropriate source to inform our decisions regarding the predominant site of service for procedures. As stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60605 through 60606), when we believe that the available data in our review process are inadequate to make a determination that a procedure should be office-based, we either make no change to the procedure's payment status or make the change temporary and reevaluate our decision using data that become available for our next evaluation. We believe that it is appropriate to continue using our judgment regarding whether the volume of cases and the proportion of cases that are provided in the physicians' office setting indicate that the procedures is an office-based procedure in addition to our medical advisors' clinical judgments, utilization data for procedures that are closely related to the procedures being evaluated, and any other information that is available to us.

While the currently available data for CPT codes 36902 and 36905 support our office-based designation proposal, we agree with the commenters that CY 2017 claims data may not be sufficiently adequate to capture the current volume and utilization for the ASC and physician office sites of service for CPT codes 36902 and 36905. Because we share commenters' concerns that the available data may not be adequate to make a determination that these procedures should be office-based, we believe it is premature to assign office-based payment for these procedures at this time. Therefore, we are not designating CPT codes 36902 and 36905 as office-based procedures for CY 2019. We will reevaluate these procedures in our CY 2020 rulemaking period. For CY 2019, these procedures will retain their current payment indicator, ''G2.''

We did not receive any public comments related to our proposal to designate CPT codes 31573 (Laryngoscopy, flexible; with therapeutic injection(s) (*e.g.,* chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral) and 36513 (Therapeutic apheresis; for platelets) as office-based procedures. Therefore, we are finalizing our proposal, without modification, to designate CPT codes 31573 and 36513 as permanently office-based procedures. However, in response to public comments we received, we are not finalizing our proposal to designate CPT codes 36902 and 36905 as office-based. CPT codes 36902 and 36905 will retain the same payment indicator, ''G2'', that the procedures were assigned in CY 2018. We intend to reevaluate these using the most recent available volume and utilization data procedures in our CY 2020 rulemaking period. The procedures we are designating as permanently office-based beginning in CY 2019 are listed in Table 56 below.

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TABLE 56.—ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2019

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	CY 2019 ASC Payment Indicator*
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral	G2	P3
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated.	P2	P2
36513	Therapeutic apheresis; for platelets	G2	R2
36901	Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report.	P2	P3
G0429	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	P3	P3

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS final rates. Current law specifies a 0.25 percent update to the PFS payment rates for CY 2019. For a discussion of the PFS rates, we refer readers to the CY 2019 PFS final rule with comment period.

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We also reviewed CY 2017 volume and utilization data and other information for 10 procedures designated as temporarily office-based in Tables 84 and 85 in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59408). Of these 10 procedures, there were very few claims in our data and no claims data for 4 procedures described by CPT codes 38222, 65785, 67229, and 0402T. Consequently, we proposed to maintain the temporary office-based designations for these 4 CPT codes for CY 2019. We included codes for which we proposed to maintain the temporary office-based designations for CY 2019 in Table 38 of the proposed rule which listed the covered surgical procedures we designated as temporary office-based in the CY 2018 OPPS/ASC final rule with comment period. The procedures for which the proposed office-based designations for CY 2019 are temporary also were indicated by asterisks in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

The volume and utilization data for 3 procedures that have a temporary office-based designation for CY 2018, described by CPT codes 36473 and 36901 and HCPCS code G0429, are sufficient to indicate that these procedures are performed predominantly in physicians' offices and, therefore, should be assigned an office-based payment indicator in CY 2019. Consequently, we proposed to designate these procedures as permanently office based and assign payment indicator ''P2'', ''P3'', ''R2'' to these covered surgical procedure codes in CY 2019. These procedures are displayed above in Table 56. The volume and utilization data for the remaining three procedures that have a temporary office-based designation for CY 2018, described by CPT codes 10030, 64461, and 64463, are sufficient

to indicate that these covered surgical procedures were not performed predominantly in physicians' offices and, therefore, should be assigned non-office-based payment indicator ''G2'' in CY 2019.

Comment: One commenter requested that CMS exempt CPT code 36901 from the office-based designation, similar to the existing office-based exemptions for certain nuclear medicine procedures (CPT codes 78000 through 78999) as well as ancillary radiology services that use a contrast agent as codified under 42 CFR 416.171(d). The commenter suggested that the payment volatility over the past several years would limit patient access to vascular access services in the ASC setting and encourage the migration of these services to the more expensive hospital setting.

Response: We do not believe establishing an office-based exemption for CPT code 36901 is warranted. We note that the exceptions for certain nuclear medicine procedures and for ancillary radiology services that use a contrast agent are exceptions to our policy governing payment for covered ancillary radiology services, not exceptions to our office-based policy. In addition, as stated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), we established the exemption to our policy governing payment for covered ancillary radiology services for certain nuclear medicine procedures (CPT codes 78000 through 78999) because the PFS nonfacility PE RVU amounts did not reflect the diagnostic radiopharmaceutical costs which are paid separately under the MPFS. In addition, as stated in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74429 through 74430), because the same issue exists for radiology procedures that use contrast agents (the contrast agent is packaged under the ASC payment system but is separately paid under the MPFS), we also exempted radiology services that use contrast agents from this policy, so that payment for these procedures will be based on the OPPS relative payment weight which includes the cost for the contrast agent.

Because its predecessor code was office-based, we have designated CPT code 36901 as office-based since it was established in CY 2017. As stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59407), we reviewed the clinical characteristics, utilization, and volume of related codes and determined that the procedure described by CPT code 36901 would be predominantly performed in physician offices. However, because we did not have utilization data for this procedure, we made the office-based designation temporary rather than permanent for CY 2018. Our review of the CY 2017 volume and utilization data indicates that CPT code 36901 is performed 54 percent of the time in physicians' offices. Our policy is to designate as office-based those procedures that are performed more than 50 percent of the time in physicians' offices. We do not believe that there is a justification for exempting this procedure from office-based status for CY 2019. Therefore, we are designating CPT code 36901 as permanently office-based for CY 2019 as proposed.

While we assigned CPT codes 10030, 64461, and 64463 payment indicators of ''G2'' (Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in Table 38 of the CY 2019 OPPS/ASC proposed rule, we inadvertently indicated in the preamble of the proposed rule that those were office-based procedures (83 FR 37156). We are not designating CPT codes 10030, 64461, and 64463 as office-based procedures for CY 2019 and are finalizing our payment indicator of ''G2'' for such procedures. We note that we did not receive any public comments on these codes.

After consideration of the public comment we received, we are finalizing our proposal, with modification, to designate the procedures shown in Table 57 below as temporarily office-based for CY 2019.

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TABLE 57.—CY 2019 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2018 OPPS/ASC FINAL RULE WITH COMMENT PERIOD AND DESIGNATED TEMPORARILY OFFICE-BASED IN THE CY 2019 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2019 CPT/HCPCS Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	CY 2019 ASC Payment Indicator*
38222	Diagnostic bone marrow; biopsy(ies) and aspiration(s)	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea (including removal of the corneal epithelium and intraoperative pachymetry when performed)	R2	R2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. Current law specifies a 0.25 percent update to the PFS payment rates for CY 2019. For a discussion of the PFS rates, we refer readers to the CY 2019 PFS final rule with comment period.

For CY 2019, we proposed to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporarily office-based, as displayed in Table 39 of the proposed rule. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures described by the new CPT codes would be predominantly performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new CPT codes, we proposed to make the office-based designation temporary rather than permanent, and stated that we will reevaluate the procedures when data become available. The procedures for which the proposed office-based designation for CY 2019 is temporary were indicated by asterisks in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to designate the procedures shown in Table 58 below as temporarily office-based. The procedures for which the office-based designation for CY 2019 is temporary are indicated by an asterisk in Addendum AA to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 58.—CY 2019 PAYMENT INDICATORS FOR NEW CY 2019 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2019 OPPS/ASC proposed rule 5-digit CMS placeholder code	Final CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2019 ASC Payment Indicator**
06X1T	0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2
10X12	10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3
10X14	10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3
10X16	10009	Fine needle aspiration biopsy, including CT guidance; first lesion	P2
10X18	10011	Fine needle aspiration biopsy, including MR guidance; first lesion	R2
11X02	11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3
11X04	11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2
11X06	11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3

** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS final rates. Current law specifies a 0.25 percent update to the PFS payment rates for CY 2019. For a discussion of the MPFS rates, we refer readers to the CY 2019 PFS final rule with comment period.

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b. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we implemented a payment methodology for calculating the ASC payment rates for covered surgical procedures that are designated as device-intensive.

According to this ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology (which does not include the C–APC methodology) to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system.

We also finalized in the CY 2017 OPPS/ASC final rule that device-intensive procedures will be subject to all of the payment policies applicable to procedures designated as an ASC device-intensive procedure under our established methodology, including our policies on no cost/full credit and partial credit devices and discontinued procedures.

In addition, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79739 through 79740), we adopted a policy for new HCPCS codes describing procedures involving the implantation of medical devices that do not yet have associated claims data, to designate these procedures as device-intensive with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent is not calculated from claims data; instead, it

is applied as a default until claims data are available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that involve the implantation of medical devices would be to ensure ASC access for new procedures until claims data become available. However, in certain rare instances, for example, in the case of a very expensive implantable device, we indicated we might temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer. Once claims data are available for a new procedure involving the implantation of a medical device, the device-intensive designation is applied to the code if the HCPCS code device offset is greater than 40 percent, according to our policy of determining device-intensive status, by calculating the HCPCS code-level device offset.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37158), we noted that, as discussed in section IV.B.2. of the proposed rule, for CY 2019 we proposed to modify our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We proposed to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we proposed to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we proposed that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we proposed that the default device offset for new codes that describe procedures that involve the implantation of medical devices would be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we proposed that the default device offset would be applied in the same manner as proposed in section IV.B.2. of the proposed rule. We proposed to amend § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also proposed in section IV.B.2. of the proposed rule, to further align the device-intensive policy with the criteria used for device pass-through status, we proposed to specify, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

(a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on our proposed modifications to our device-intensive criteria, for CY 2019, we proposed to update the ASC CPL that are eligible for payment according to our proposed device-intensive procedure payment methodology, reflecting the proposed individual HCPCS code device-offset percentages based on CY 2017 OPPS claims and cost report data available for the proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2019, were assigned payment indicator ''J8'' and were included in ASC Addendum AA to the proposed rule (which is available on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2019 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device intensive also are included in Addendum AA to the proposed rule. In addition, for CY 2019, we proposed to only apply our proposed device-intensive procedure payment methodology to device-intensive procedures under the ASC payment system when the device-intensive procedure is furnished with a surgically inserted or implanted device (including single use medical devices). Under this proposal, the payment rate under the ASC payment system for device-intensive procedures furnished without an implantable or inserted medical device would be calculated by applying the uniform ASC conversion factor to both the device portion and service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure and summing both portions (device and service) to establish the ASC payment rate.

Comment: The majority of commenters supported the proposal to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent. The commenters believed that the proposed policy change will encourage migration of services into the high-quality, less-expensive ASC setting, resulting in cost savings to the Medicare program and Medicare beneficiaries. Some of these commenters encouraged CMS to further modify its proposal and instead lower the device offset percentage threshold for procedures to qualify as device-intensive to 25 percent instead of 30 percent.

Response: We appreciate commenters' support. At this time, we continue to believe that applying a device offset percentage threshold of greater than 30 percent for procedures to qualify as device-intensive is most appropriate for the reasons described in our original proposal. We will take commenters' suggestion of applying a device offset percentage threshold of greater than 25 percent for procedures to qualify as device-intensive into consideration for future rulemaking.

Comment: The majority of commenters supported CMS proposal to modify the device-intensive criteria to allow procedures that involve single-use devices, regardless of whether they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures. The commenters believed that this proposed policy change will better support accurate payment for procedures where an implantable device is a significant proportion of total costs and, ultimately, will spur innovation.

Response: We appreciate the commenters' support.

Comment: One commenter requested that CMS assign device-intensive status, payment indicator ''J8'', to CPT codes 0410T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only), 0411T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only), and 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only).

Response: We agree with the commenter's request and have assigned CPT codes 0410T, 0411T, and 0414T to payment indicator ''J8'' for CY 2019. These CPT codes represent procedures requiring the implantation of medical devices that do not yet have associated claims data and therefore have been granted device-intensive status with our current default device offset percentage of 31 percent, in accordance with our current policy outlined in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658).

Comment: A few commenters suggested that CMS only adjust the non-device portion of the payment by the wage index, consistent with the Agency's policy for separately payable drugs and biologicals.

Response: In response to the commenters' suggestion that CMS only adjust the non-device portion of the payment by the wage index, we note that such a policy would increase payment for providers with a relatively low wage index (that is, a wage index value of less than 1) and decrease it for providers with a relatively high wage index (that is, a wage index value of greater than 1), and that we did not make such a proposal. However, we will take this comment into consideration for future rulemaking.

Comment: A few commenters urged CMS to calculate the device offset percentage for potential device-intensive procedures using the standard (non-comprehensive APC) ASC ratesetting methodology and to assign device-intensive status in the ASC system based on that device offset percentage because they believed it is more consistent with the overall ASC payment system. One commenter requested some clarification in the final rule with comment period about CMS' current methodology for calculating the device offset percentage for device-intensive procedures and specifically asked that CMS:

- Confirm that the ASC device-intensive status as assigned by CMS is based on the offset calculated according to the ASC rate setting methodology;
- Disclose what offset data (meaning the calculation methodology used) appears in the second spreadsheet of Addendum P titled ''2019 NPRM HCPCS Offsets'';
- Display the device offsets, in future rulemaking, based on the ASC methodology and not the OPPS methodology if the offset data displayed in the second spreadsheet of Addendum P is based on the OPPS methodology and device-intensive status is based on the ASC methodology; and
- Modify the second worksheet of Addendum P titled ''2019 NPRM HCPCS Offsets'' to only include the codes for procedures that employ implantable and insertable devices and exclude all of the irrelevant codes that do not employ implantable or insertable devices.

Response: As stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37158), according to our established ASC payment methodology, we apply the device offset percentage based on the standard OPPS APC ratesetting methodology (which does not include the C–APC methodology) to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system.

In response to commenter's questions and suggestions relating to Addendum P, we note that the device offset percentages reflected in both worksheets of Addendum P are based upon the OPPS C–APC methodology. We believe this is appropriate as Addendum P is created to display the device offsets, device offset percentages, and device-intensive codes under the OPPS. Specific to the commenter's suggestion that we modify the second worksheet of Addendum P titled ''2019 NPRM HCPCS Offsets'' to only include the codes for procedures that employ implantable and insertable devices and exclude all of the codes that do not employ implantable or insertable devices, we note that the second worksheet of Addendum P is intended to display the device offsets and device offset percentages for all codes for which we have such data for under the OPPS. The applicable device offset percentages for the ASC payment system are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html* under the revised title of ''CY 2019 Final ASC Device Offset Percentages and Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies.''

Comment: Commenters supported the existing policy of granting device-intensive status and applying a default device offset to procedures requiring devices that do not yet have claims data, as well as the proposal to use claims data from clinically similar and related codes to establish device offsets for procedures with new codes that do not have direct predecessor codes according to CPT.

Response: We appreciate the commenters' support.

Comment: Commenters supported CMS' proposed device-intensive status for CPT codes:

- 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method);
- 28730 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse;);
- 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint);
- 36903 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report; with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis segment);
- 36904 (Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic

angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s);); and

• 36906 (Percutaneous transluminal mechanical thrombectomy and/or infusion for thrombolysis, dialysis circuit, any method, including all imaging and radiological supervision and interpretation, diagnostic angiography, fluoroscopic guidance, catheter placement(s), and intraprocedural pharmacological thrombolytic injection(s); with transcatheter placement of intravascular stent(s), peripheral dialysis segment, including all imaging and radiological supervision and interpretation necessary to perform the stenting, and all angioplasty within the peripheral dialysis circuit).

Other commenters requested that CMS assign device-intensive status to—

• HCPCS code C9747 (Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance);

• CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed), 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (*e.g.,* fluoroscopic, ct), single or multiple levels, unilateral or bilateral; lumbar);

• CPT code 55874 (Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed);

• CPT code 0409T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only);

• CPT code 0410T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only);

• CPT code 0411T (Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only); and

• CPT code 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only).

Response: We appreciate the commenters' support. With respect to the commenters' request that we assign the device-intensive designation to HCPCS code C9747 and CPT codes 43210, 0275T, and 55874, we note that the device offset percentage for all four of these procedures (as identified by the above mentioned HCPCS codes or predecessor codes) is not above the 30-percent threshold, and therefore these procedures are not eligible to be assigned device-intensive status.

CPT codes 0409T, 0410T, 0411T, and 0414T were inadvertently omitted from the listing of proposed device-intensive procedures in the CY 2019 OPPS/ASC proposed rule. We are including them as device-intensive procedures in this final rule with comment period. CPT code 36904 was proposed as a device-intensive procedure. However, using the most currently available data for this CY 2019 OPPS/ASC final rule with comment period, we determined that its device offset percentage is not above the 30-percent threshold, and therefore this procedure is not eligible to be assigned device-intensive status.

For new codes describing procedures that are payable when furnished in an ASC involving the implantation of a medical device, we proposed that the default device offset would be applied in the same manner as proposed in section IV.B.2. of the proposed rule.

In addition, as also discussed in section IV.B.2. of this final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through payment status, we are finalizing our proposal to specify, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

• Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

• Is an integral part of the service furnished;

• Is used for one patient only;

• Comes in contact with human tissue;

• Is surgically implanted or inserted (either permanently or temporarily); and

• Is not any of the following:

(a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In conjunction with our modifications to the device-intensive criteria, we are finalizing our proposal, without modification, to amend § 416.171(b)(2) of the regulations to reflect three new device criteria.

After consideration of the public comments we received, we are finalizing our proposal to modify our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We are finalizing our proposal to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we are finalizing our proposal to modify our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we are finalizing our proposal that device-intensive procedures would be subject to the following criteria:

• All procedures must involve implantable devices assigned a CPT or HCPCS code;

• The required devices (including single-use devices) must be surgically inserted or implanted; and

• The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we proposed that the default device offset for new codes that describe procedures that involve the implantation of medical devices would be 31 percent beginning in CY 2019.

Further, after consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA as device-intensive and subject to the device-intensive procedure payment methodology for CY 2019.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted in ASCs at no cost/full credit or partial credit, as set forth in § 416.179 of our regulations, is consistent with the OPPS policy that was in effect until CY 2014. Specifically, the OPPS policy that was

in effect through CY 2013 provided a reduction in OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device (77 FR 68356 through 68358). The established ASC policy reduces payment to ASCs when a specified device is furnished without cost or with full credit or partial credit for the cost of the device for those ASC covered surgical procedures that are assigned to APCs under the OPPS to which this policy applies. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68742 through 68744) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37159), we noted that, as discussed in section IV.B. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75006), we finalized our proposal to modify our former policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. Formerly, under the OPPS, our policy was to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnished a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital received partial credit in the amount of 50 percent or more (but less than 100 percent) of the cost for the specified device. For CY 2014, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a replaced device, capped at the device offset amount.

Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in that final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

All ASC covered device-intensive procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37159 through 37160), for partial credit, we proposed to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC would append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) Submitting the claim for the device replacement procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

We did not receive any public comment on these proposals. Therefore, we are finalizing these proposals without modification. Specifically, we will apply the HCPCS ''FB''/''FC'' modifier policy to all device-intensive procedures in CY 2019. For CY 2019, we will reduce the payment for the procedures in the ASC device adjustment file by the full device offset amount if a device is furnished without cost or with full credit. ASCs must append the HCPCS modifier ''FB'' to the HCPCS code for a surgical procedure listed in the ASC device adjustment file previously mentioned when the device is furnished without cost or with full credit. In addition, for CY 2019, we will reduce the payment for the procedures listed in the ASC device adjustment file by one-half of the device offset amount if a device is provided with partial credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the device cost. The ASC must append the HCPCS ''FC'' modifier to the HCPCS code for a surgical procedure listed in the ASC device adjustment file when facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device.

The CPT code, the CPT code short descriptor, the final CY 2019 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy will apply are included in the ASC policy file labeled ''CY 2019 Final ASC Device Offset Percentages and Procedures to which the No Cost/Full Credit and Partial Credit Device Adjustment Policy Applies'', which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare?medicare-Fee-for-Service-Payment/ASCPayment/ASC-Policy-Files.html*.

d. Additions to the List of ASC Covered Surgical Procedures

As discussed in section XII.A.3. of the proposed rule (83 FR 37159), we proposed to revise our definition of surgery for CY 2019 to include certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range. For CY 2019, we proposed to include procedures that are described by Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in

the Category I CPT code surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We also are continuing to include in our definition of surgical procedures those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS. As discussed in section XII.A.3. of this final rule with comment period, we are finalizing our proposal to revise our definition of ''surgery'' for CY 2019 and subsequent years to include procedures that are described by Category I CPT codes that are not in the CPT surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

We conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC CPL, and that meet our proposed definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, we proposed to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019, as shown in Table 40 of the proposed rule (83 FR 37160). After reviewing the clinical characteristics of these procedures and consulting with stakeholders and our clinical advisors, we determined that these 12 procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. Our regulation at 42 CFR 416.166(c) lists general exclusions from the list of ASC covered surgical procedures based primarily on factors relating to safety, including procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, or directly involve major blood vessels. We have assessed each of the proposed added procedures against the regulatory safety criteria and believe that these procedures meet each of the criteria. Although the proposed cardiac catheterization procedures may involve blood vessels that could be considered major, based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe these procedures may be appropriately performed in an ASC. Therefore, we proposed to include these 12 procedures on the list of ASC covered surgical procedures for CY 2019.

As stated in the August 2, 2007 ASC final rule (72 FR 42481), we believe the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures, and we do not believe that it is logically or clinically consistent to exclude certain cardiac procedures from the list of ASC covered surgical procedures on the basis of the involvement of major blood vessels, yet continue to provide ASC payment for similar procedures involving major blood vessels that have a history of safe performance in ASCs, such as CPT code 36473 (Mechanicochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance) and CPT code 37223 (Insertion of stents into groin artery, endovascular, accessed through the skin or open procedure). However, in the CY 2019 proposed rule, we stated that we were interested in hearing any specific safety concerns from stakeholders regarding these 12 cardiac catheterization procedures and requested comments on whether these procedures may be safely performed in an ASC in light of the regulatory criteria governing which procedures may be added to the ASC covered procedures list.

Comment: The majority of commenters supported the proposal to add 12 cardiac catheterization procedures to the list of ASC covered surgical procedures. Commenters noted that these procedures may be performed in a physician office setting, would not inherently pose a significant risk to beneficiary safety or require active medical monitoring at midnight following the procedure, and are regularly performed on commercial patients in the ASC setting. The commenters also noted that many of these services are currently provided in a hospital outpatient setting and, therefore, the Medicare program and beneficiaries would achieve savings to the extent such services migrate to the ASC setting.

Some commenters were concerned that the proposal would expose beneficiaries to significant risks. The commenters noted that certain cardiac catheterization procedures may reveal blockages in the coronary arteries that require an immediate intervention involving hospital-level care. One commenter requested that CMS ensure that the same facility standards that apply to hospital-based cardiac catheterization laboratories also apply to ASCs performing these services. The commenter further stated that CMS should not add any cardiac catheterization procedures to the list of ASC covered services until it has ensured that the conditions of coverage and accreditation requirements that would be applied to ASCs furnishing such services are at least as stringent as the standards applied to hospital cardiac catheterization labs, with additional attention to the issues created by engaging in procedures involving the major vessels and the heart without the immediate accessibility of the facilities of an acute care hospital. In addition, the commenters suggested that the proposal may lead to ''cherry-picking'' with a sicker, more complex, and higher cost patient population being treated in the hospital outpatient setting.

Response: We appreciate the commenters' support. We disagree with the commenters that our proposal to add 12 cardiac catheterization procedures would expose beneficiaries to significant risks. As noted by many of the commenters, many of these procedures are already performed safely in the physician's office setting. The procedures have been reviewed by CMS medical officers and we have assessed each against the regulatory safety criteria and believe that they meet all of those criteria. Further, we believe these procedures are clinically similar to peripheral endovascular procedures which are already currently included on the ASC CPL.

As stated in the proposed rule, although the proposed cardiac catheterization procedures may involve blood vessels that could be considered major, based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe these procedures may be appropriately performed in an ASC. While we acknowledge that it may be more appropriate for certain beneficiaries to receive these procedures in a hospital-level setting, which typically have a greater range of items and services available when compared

to an ASC setting, including onsite cardiac surgery backup, we believe that many beneficiaries could be ideal candidates to receive these services in an ASC setting and that beneficiaries and their physicians should be able to choose an appropriate site of service for surgeries based on the clinical characteristics of the patient and other factors. We also note that our conditions of coverage for ASCs, including 42 CFR 416.42, require surgical procedures to be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

While we agree with commenters that a relatively healthier and less complex Medicare patient population would, in general, be a more ideal patient population to receive cardiac catheterization procedures in an ASC setting, we disagree that we should prohibit such procedures on that basis. We believe that relatively healthy and less complex patients would benefit from the shorter length of stay and reduced cost-sharing that would be expected in an ASC setting.

Comment: Commenters recommended that CMS add additional cardiovascular procedures that are related to the proposed additions to the ASC CPL. The commenters' recommended codes are shown in Table 59 below.

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TABLE 59.—CARDIOVASCULAR PROCEDURES REQUESTED BY COMMENTERS FOR ADDITION TO THE CY 2019 LIST OF ASC COVERED SURGICAL PROCEDURES

CY 2019 CPT Code	CY 2019 Long Descriptor
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)
92960	Cardioversion, elective, electrical conversion of arrhythmia; external
92973	Percutaneous transluminal coronary thrombectomy mechanical (list separately in addition to code for primary procedure)
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (list separately in addition to code for primary procedure)
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)

CY 2019 CPT Code	CY 2019 Long Descriptor
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system
93312	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report
93313	Echocardiography, transesophageal, real-time with image documentation (2d) (with or without m-mode recording); placement of transesophageal probe only
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only
93463	Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (list separately in addition to code for primary procedure)
93464	Physiologic exercise study (eg, bicycle or arm ergometry) including assessing hemodynamic measurements before and after (list separately in addition to code for primary procedure)
93505	Endomyocardial biopsy
93530	Right heart catheterization, for congenital cardiac anomalies
93531	Combined right heart catheterization and retrograde left heart catheterization, for congenital cardiac anomalies
93532	Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies

CY 2019 CPT Code	CY 2019 Long Descriptor
93533	Combined right heart catheterization and transseptal left heart catheterization through existing septal opening, with or without retrograde left heart catheterization, for congenital cardiac anomalies
93561	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement (separate procedure)
93562	Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (list separately in addition to code for primary procedure)
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed (list separately in addition to code for primary procedure)
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (list separately in addition to code for primary procedure)
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (list separately in addition to code for primary procedure)
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (list separately in addition to code for primary procedure)
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (list separately in addition to code for primary procedure)
93571	Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure)

CY 2019 CPT Code	CY 2019 Long Descriptor
93572	Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure)
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)

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Response: We appreciate the commenters' recommendations for procedures that may be suitable candidates for addition to the list of ASC covered surgical procedures. We have reviewed the recommended procedures and believe some procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, and are separately paid under the OPPS. Therefore, we are accepting the commenters' recommendation, in part, to include the following procedures to our list of ASC covered surgical procedures:

- CPT code 93566 (Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (list separately in addition to code for primary procedure));
- CPT code 93567 Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (list separately in addition to code for primary procedure);
- CPT code 93568 (Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (list separately in addition to code for primary procedure));
- CPT code 93571 Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure);
- CPT code 93572 Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure).

However, we do not believe that the remaining procedures displayed in Table 59 above meet the criteria to be added to the ASC CPL. If new evidence, clinical studies, or data become available that may support adding such procedures to the ASC CPL, we will

consider the commenters' recommendations in future rulemaking.

Comment: Commenters recommended that CMS add several additional procedures to the covered surgical procedures list that were not proposed to be added to the ASC CPL. These included discography, wound therapy, joint replacement, urological, gastroenterological, and peripheral arterial disease diagnostic procedures. Some commenters suggested that any procedure that is payable under the OPPS should automatically be added to the ASC CPL.

Response: We appreciate the commenters' recommendations. Based on our review, we did not determine that any of these procedures should be added to the ASC CPL for CY 2019, however, we recognize that ongoing review is necessary to determine if changes in technology and/or medical practice affect the clinical appropriateness of these procedures for the ASC setting. Accordingly, while we are not adding the recommended procedures to the ASC CPL for CY 2019, we will take these public comments into consideration in future rulemaking. With respect to automatically adding procedures that are payable under the OPPS, we note that we must evaluate each procedure against the regulatory criteria for inclusion on the ASC CPL; therefore, we are not accepting this recommendation.

After consideration of the public comments we received, we are finalizing our proposal to add 12 cardiac catheterization procedures to the list of ASC covered surgical procedures. In addition, based on public comments, we are adding five procedures performed during cardiac catheterization procedures to the list of ASC covered surgical procedures (CPT codes 93566, 93567, 93568, 93571, and 93572). We believe these procedures would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure and are separately paid under the OPPS. The 17 procedures that we are adding to the ASC CPL, including the long code descriptors and the final CY 2019 payment indicators, are displayed in Table 60 below.

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TABLE 60.—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2019

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2019 ASC Payment Indicator
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed	G2
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	G2
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;	G2
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography	G2
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization	G2
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization	G2
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	G2

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2019 ASC Payment Indicator
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	G2
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	G2
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	G2
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (list separately in addition to code for primary procedure)	N1
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (list separately in addition to code for primary procedure)	N1
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (list separately in addition to code for primary procedure)	N1
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (list separately in addition to code for primary procedure)	N1

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2019 ASC Payment Indicator
93571	Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure)	N1
93572	Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure)	N1

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e. Review of Recently Added Procedures to the ASC Covered Procedures List

Section 1833(i)(1) of the Act requires us to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. As noted in section XII.C.1. of the CY 2019 OPPS/ASC proposed rule, we evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders. Often, when a procedure is added to the ASC CPL, the provider community has limited experience in performing the procedure on the Medicare population, even if providers have greater experience with other patient populations. Because ASCs generally provide a subset of items and services that are offered by hospitals and because Medicare beneficiaries tend to be frailer and exhibit a higher number of comorbidities than other populations, we believe it may be appropriate to reevaluate recently added procedures.

Specifically, in the CY 2019 OPPS/ASC proposed rule (83 FR 37161 through 37162), we proposed to review all procedures that were added to the ASC CPL within the 3 calendar years prior to the year in which we are engaging in rulemaking to assess the safety, effectiveness, and beneficiary experience of these newly added procedures when performed in the ASC setting. Our review began with procedures added to the ASC CPL in CYs 2015, 2016, and 2017, to assess whether newly added procedures continue to meet our criteria, including whether they continue not to be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC and continue not to be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. This review included taking into account recent clinical developments and available safety findings related to the recently added procedures.

We proposed to review all 38 procedures that were added to the ASC CPL for CYs 2015, 2016, and 2017. The 38 procedures that were added to the ASC CPL during this time were displayed in Table 41 of the proposed rule (82 FR 37161 through 37162), along with their HCPCS code long descriptors, the CY 2018 payment indicators, and the calendar year that each procedure was added to the ASC CPL. We also sought public comment about these recently added procedures from members of the public, including Medicare beneficiaries, ASCs, and physicians performing these procedures in the ASC setting. In addition, we sought public comment on whether these procedures continue to meet the criteria to remain on the ASC CPL. We stated our intent to evaluate each of these 38 procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any public comments we received to determine whether they continue to meet the criteria to be a covered surgical procedure.

In addition, we solicited public comment regarding how our systematic review should be structured in the future, including the length of time procedures should be considered recently added, how frequently reviews should be performed in light of the time required to accumulate meaningful data and whether any future reviews should examine procedures added during a period of time greater or less than the previous 3 completed calendar years.

Comment: Many commenters supported the proposal to review procedures that were recently added to the ASC CPL. A number of commenters (patients and providers) noted that the procedures shown in Table 41 of the proposed rule can be safely and effectively performed in an ASC setting and recommended retaining the procedures on the ASC CPL. One commenter also noted that CPT codes 0171T (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level) and 0172T (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level) were deleted as of January 1, 2017.

A number of commenters believed there may not be enough data on the 38 procedures to adequately assess if the procedures continue to meet the criteria to remain on the ASC CPL. The commenters recommended reviewing procedures on the CPL after the procedure has been added to the CPL for a minimum of 3 to 5 years.

Further, commenters requested additional information regarding the methodology and supporting materials that CMS would use to determine that a procedure should no longer remain on the ASC CPL. The commenters requested that stakeholders receive appropriate notice that CMS is

proposing to remove a procedure so that stakeholders have an opportunity to comment.

Response: We appreciate the commenters' feedback regarding the safety and efficacy of these procedures in the ASC setting. We note that we did not receive any public comments in support of removing these recently added procedures from the ASC CPL.

We note that CPT codes 0171T and 0172T were inadvertently included in Table 41 of the proposed rule. These codes were deleted effective January 1, 2017, and no longer remain on the ASC CPL. In our evaluation of the remaining 36 procedures, we did not find any clinical evidence, data, or other materials to justify removing these procedures from the ASC CPL. Therefore, for CY 2019, we are not removing any of the remaining 36 procedures displayed in Table 41 of the proposed rule from the ASC CPL.

In response to commenters' recommendation to wait a minimum of 3 to 5 years to assess whether a procedure meets our criteria to remain on the ASC CPL, we agree that a longer timeframe may provide better data to adequately determine whether or not the procedure meets our criteria. We will consider the commenters' recommendations in future rulemaking.

In response to the commenters' request for additional information regarding the methodology and supporting materials that we would use to determine that a procedure no longer meets the criteria to remain on the ASC CPL, we note that in the CY 2019 OPPS/ASC proposed rule (83 FR 37161), we stated our intent to evaluate each of the procedures using all available data, including clinical characteristics, utilization reflected in ASC claims and pricing data, prevailing medical practice, and any public comments we receive.

After consideration of the public comments we received, we are retaining the procedures displayed in Table 61 on the ASC CPL for CY 2019, with the exception of CPT codes 0171T and 0172T, which were deleted from the ASC CPL effective January 1, 2017 and, therefore, will not be included on the ASC CPL for CY 2019. However, based on the public comments we received about the re-review process generally, we do not believe it is necessary to finalize any proposal regarding ongoing reviews of recently added procedures at this time. Rather, we will take all commenters' suggestions into account as we consider future refinements to our review of the ASC CPL.

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TABLE 61.—ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2015, 2016, AND 2017

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
0171T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; single level	J8	2016	CPT code deleted
0172T	Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar; each additional level	N1	2016	CPT code deleted
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
20938	Autograft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2	J8	2015	Will remain on ASC CPL
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below c2, each additional interspace (list separately in addition to code for separate procedure)	N1	2017	Will remain on ASC CPL
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below c2	J8	2015	Will remain on ASC CPL
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	J8	2015	Will remain on ASC CPL
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure)	N1	2015	Will remain on ASC CPL
22840	Posterior non-segmental instrumentation (eg, harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at c1, facet screw fixation) (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
22842	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
22845	Anterior instrumentation; 2 to 3 vertebral segments (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (list separately in addition to code for primary procedure)	N1	2017	Will remain on ASC CPL
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	J8	2016	Will remain on ASC CPL
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	J8	2016	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction	J8	2016	Will remain on ASC CPL
49406	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, percutaneous	G2	2016	Will remain on ASC CPL
57120	Colpocleisis (le fort type)	G2	2016	Will remain on ASC CPL
57310	Closure of urethrovaginal fistula;	G2	2016	Will remain on ASC CPL
58260	Vaginal hysterectomy, for uterus 250 g or less;	G2	2016	Will remain on ASC CPL
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	G2	2016	Will remain on ASC CPL
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	G2	2016	Will remain on ASC CPL
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2	2016	Will remain on ASC CPL
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g;	G2	2016	Will remain on ASC CPL
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2	2016	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2	2016	Will remain on ASC CPL
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical	G2	2015	Will remain on ASC CPL
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	G2	2015	Will remain on ASC CPL
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	G2	2015	Will remain on ASC CPL
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (list separately in addition to code for primary procedure)	N1	2015	Will remain on ASC CPL

CY 2019 CPT Code	CY 2019 Long Descriptor	CY 2018 ASC Payment Indicator	Calendar Year Added to ASC CPL	ASC CPL Review Results
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical	G2	2015	Will remain on ASC CPL
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic	G2	2016	Will remain on ASC CPL
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	G2	2015	Will remain on ASC CPL
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; thoracic	G2	2016	Will remain on ASC CPL
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)	G2	2015	Will remain on ASC CPL

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2. Covered Ancillary Services

In the CY 2019 OPPS/ASC proposed rule (83 FE 37163), consistent with the established ASC payment system policy (72 FR 42497), we proposed to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS. Maintaining consistency with the OPPS may result in proposed changes to ASC payment indicators for some covered ancillary services because of changes that we proposed under the OPPS for CY 2019. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2018, but is proposed for packaged status under the CY 2019 OPPS, to maintain consistency with the OPPS, we also proposed to package the ancillary service under the ASC payment system for CY 2019. We proposed to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XII.F. of the proposed rule, was used in Addendum BB to the proposed rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2019.

All ASC covered ancillary services and their proposed payment indicators for CY 2019 were included in Addendum BB to the proposed rule (which is available via the internet on the CMS website).

We did not receive any public comments on these proposals. Therefore, we are finalizing, without modification, our proposal to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS. All CY 2019 ASC covered ancillary services and their final payment indicators are included in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website).

D. ASC Payment for Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are fully described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so that the packaged device payment amount is the same as under the OPPS, and only the service portion of the rate is subject to the ASC standard ratesetting methodology. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79732 through 79753), we updated the CY 2016 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2015 data, consistent with the CY 2017 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2017 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount (we refer readers to the CY 2018 PFS proposed and final rules) or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2018 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2018 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2018 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal codes under the OPPS. Under the OPPS, a conditionally packaged code (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To address this concern, for the device removal procedures that are conditionally packaged in the OPPS (status indicator ''Q2''), we assigned the current ASC payment indicators associated with these procedures and continued to provide separate payment since CY 2014.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37163 through 37164), we proposed to update ASC payment rates for CY 2019 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of the proposed rule. Because the proposed OPPS relative payment weights are based on geometric mean costs, the ASC system would use geometric means to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of the proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2019 OPPS device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2019 MPFS nonfacility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2018, for CY 2019, we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

Comment: One commenter recommended that CMS change CPT code 0356T (Insertion of drug delivery implant into tear ducts) from payment indicator ''N1'' to ''R2.''

Response: We note that, in the CY 2019 OPPS/ASC proposed rule, we

proposed to assign CPT code 0356T a status indicator of ''Q1'' under the OPPS. As stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37163 through 37164), HCPCS codes that are conditionally packaged under the OPPS (status indicators ''Q1'' and ''Q2'') and are not a device removal procedure are always packaged (payment indicator ''N1'') under the ASC payment system. Therefore, we are finalizing our proposal to assign payment indicator ''N1'' to CPT code 0356T under the ASC payment system for CY 2019.

Comment: Several commenters disagreed with the proposed CY 2019 ASC payment rates for the surgical procedures described by the following CPT/HCPCS codes:

- CPT code 22513 (Injection of bone cement into body of middle spine bone accessed through the skin using imaging guidance);
- CPT code 22514 (Injection of bone cement into body of lower spine bone accessed through the skin using imaging guidance);
- CPT code 43210 (Diagnostic examination of esophagus, stomach, and/or upper small bowel with repair of muscle at esophagus and stomach using an endoscope);
- CPT code 62264 (Injection or mechanical removal of spinal canal scar tissue, percutaneous procedure, accessed through the skin, multiple sessions in 1 day);
- CPT code 62321 (Injection of substance into spinal canal of upper or middle back using imaging guidance);
- CPT code 62323 (Injection of substance into spinal canal of lower back or sacrum using imaging guidance);
- CPT code 62380 (Decompression of spinal cord and/or nerve root in lower back using endoscope);
- CPT code 63650 (Implantation of spinal neurostimulator electrodes, accessed through the skin);
- CPT code 63685 (Insertion of spinal neurostimulator pulse generator or receiver); and
- HCPCS code C9749 (Repair of nasal vestibular lateral wall stenosis with implant(s)).

Some commenters noted that payment rates for some of these procedures are lower than their payment levels from several years ago. Other commenters suggested that the cost of the procedure significantly exceeds Medicare's payment and questioned the validity of some of the hospital cost data on which the ASC payment rates were based.

Response: We are required by law to review and update the data on which we establish payment rates on an annual basis. The ASC payment is dependent upon the APC assignment for the procedure. Based on our analysis of the latest hospital outpatient and ASC claims data used for this final rule with comment period, we are updating ASC payment rates for CY 2019 using the established rate calculation methodologies under § 416.171 of the regulations and using our finalized modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of this final rule with comment period. We do not generally make additional payment adjustments to specific procedures. As such, we are finalizing the APC assignment and payment indicators for CPT codes 22513, 22514, 43210, 62264, 62321, 62323, 62380, 63650, 63685, and C9749.

Comment: One commenter recommended that the ASC payment system allow procedures conditionally packaged under the OPPS (status indicator ''Q1'' and ''Q2'') to be paid separately under the ASC payment system when they are performed with another procedure. The commenters also suggest that certain conditionally packaged codes are performed without another major procedure more than half of the time.

Response: Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS, and which are not device removal procedures, are always packaged (payment indicator ''N1'') under the ASC payment system, no matter how frequently they are billed without a significant procedure under the OPPS. Therefore, we are not accepting this recommendation.

Comment: One commenter recommended that CMS eliminate the prohibition against billing for services using an unlisted CPT surgical procedure code.

Response: Under 42 CFR 416.166(c)(7), covered surgical procedures do not include procedures that can only be reported using a CPT unlisted surgical procedure code. Therefore, such procedures are not payable under the ASC payment system. As discussed in the August 2, 2008 final rule (72 FR 42484 through 42486), it is not possible to know what specific procedure would be represented by an unlisted code. CMS is required to evaluate each surgical procedure for potential safety risk and the expected need for overnight monitoring and to exclude such procedures from ASC payment. It is not possible to evaluate procedures that would be reported by unlisted CPT codes according to these criteria. Therefore, we are not accepting this recommendation.

After consideration of the public comments we received, we are finalizing our proposed policies, without modification, to calculate the CY 2019 payment rates for ASC covered surgical procedures according to our established methodologies using the modified definition of device-intensive procedures. For those covered office-based surgical procedures where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the PFS nonfacility PE RVU-based amount, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2019. For a discussion of the PFS rates, we refer readers to the CY 2019 PFS final rule with comment period.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of codes that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged code describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal codes, as discussed in section IV. of the proposed rule). Thus, our policy

generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower. 42 CFR 416.171(d)(1).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent. 42 CFR 416.171(d)(2).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; 42 CFR 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Payment for Covered Ancillary Services for CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37164 through 37165), for CY 2019 and subsequent years, we proposed to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2019 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2019 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2019 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2019 were listed in Addendum BB to the proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the PFS proposed rates, the proposed payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2019. For a discussion of the PFS rates, we refer readers to the CY 2019 PFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Comment: Commenters recommended that CMS pay separately for Cysview®, HCPCS code C9275 (hexaminolevulinate HCl), similar to the proposal to pay separately for Exparel. Commenters also recommended that CMS use its equitable payment adjustment authority under section 1833(t)(2)(E) of the Act to provide a drug ''add-on'' payment for certain procedures.

Response: As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79668), we continue to believe that Cysview® is a drug that functions as a supply in a diagnostic test or procedure and therefore is packaged with payment for the surgical procedure. In the CY 2019 OPPS/ASC proposed rule, we did not propose to make any changes to the ''drugs that function as a supply in a diagnostic test or procedure'' packaging

policy or propose any drug ''add-on'' policies. Therefore, we are not accepting the commenters' recommendation.

Comment: One commenter recommended that CMS develop a policy that pays separately for drugs that are administered at the time of cataract surgery, but are not integral or necessary to the cataract procedure, and have an FDA-approved indication to treat/prevent postoperative issues.

Response: We appreciate the commenter's recommendation. We refer readers to section II.A.3. of this final rule with comment period for details related to the packaging policy for drugs that function as a supply in a surgical procedure or diagnostic test. While we did not propose such a change in the CY 2019 OPPS/ASC proposed rule, we will consider this recommendation in future rulemaking.

3. CY 2019 ASC Packaging Policy for Non-Opioid Pain Management Treatments

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters expressed a variety of views on packaging under the OPPS. In the CY 2018 OPPS/ASC final rule with comment period, we summarized the comments received in response to our request (82 FR 59255). The comments ranged from requests to unpackage most items and services that are either conditionally or unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device. We stated in the CY 2018 OPPS/ASC final rule with comment period that CMS would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission) recently recommended that CMS examine payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments. The Commission was established in 2017 to study ways to combat and treat drug abuse, addiction, and the opioid crisis. The Commission's report [87] included a recommendation for CMS to ''review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain. . . .'' [88] With respect to the packaging policy, the Commission's report states that ''the current CMS payment policy for 'supplies' related to surgical procedures creates unintended incentives to prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all 'surgical supplies,' which includes hospital-administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not.'' [89] HHS also presented an Opioid Strategy in April 2017 [90] that aims in part to support cutting-edge research and advance the practice of pain management. On October 26, 2017, the opioid crisis was declared a national public health emergency under Federal law [91] and this determination was renewed on April 20, 2018.[92]

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37067 through 37071), in response to stakeholder comments on the CY 2018 OPPS/ASC proposed rule and in light of the recommendations regarding payment policies for certain drugs, we recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. Currently, as noted above, drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of the costs of the drugs. The costs associated with packaged drugs that function as a supply are included in the ratesetting methodology for the surgical procedures with which they are billed and the payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services to the extent they are billed with the procedure. In our evaluation, we used currently available data to analyze the utilization patterns associated with specific drugs that function as a supply over a 5-year time period (CYs 2013 through 2017) to determine whether this packaging policy has reduced the use of these drugs. If the packaging policy discouraged the use of drugs that function as a supply or impeded access to these products, we would expect to see a significant decline in utilization of these drugs over time, although we note that a decline in utilization could also reflect other factors, such as the availability of alternative products. We did not observe significant declines in the total number of units used in the hospital outpatient department for a majority of the drugs included in our analysis.

In fact, under the OPPS, we observed the opposite effect for several drugs that function as a supply, including Exparel (HCPCS code C9290). Exparel is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In 2011, Exparel was approved by the FDA for administration into the postsurgical site to provide postsurgical analgesia.[93] Exparel had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period. Beginning in CY 2015, Exparel was packaged as a surgical supply under both the OPPS and the ASC payment system. Exparel is currently the only non-opioid pain management drug that is packaged as a drug that functions as a supply when used in a surgical procedure under the OPPS and the ASC payment system.

From CYs 2013 through 2017, there was an overall increase in the OPPS Medicare utilization of Exparel of approximately 229 percent (from 2.3 million units to 7.7 million units) during this 5-year time period. The total number of claims reporting Exparel

[87] President's Commission on Combating Drug Addiction and the Opioid Crisis, Report (2017). Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[88] Ibid, at page 57, Recommendation 19.

[89] Ibid.

[90] Available at: *https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html.*

[91] Available at: *https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.*

[92] Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[93] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s000lbl.pdf.*

increased by 222 percent (from 10,609 claims to 34,183 claims) over this time period. This increase in utilization continued, even after the 3-year drug pass-through payment period ended for this product in 2014, with 18 percent overall growth in the total number of units used from CYs 2015 through 2017 (from 6.5 million units to 7.7 million units). The number of claims reporting Exparel increased by 21 percent during this time period (from 28,166 claims to 34,183 claims).

Thus, we have not found evidence to support the notion that the OPPS packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department. Therefore, based on this data analysis, we stated in the CY 2019 OPPS/ASC proposed rule that we did not believe that changes were necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply when used in a surgical procedure in this setting at this time.

In terms of Exparel in particular, we have received several requests to pay separately for the drug rather than packaging payment for it as a surgical supply. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66874 and 66875), in response to comments from stakeholders requesting separate payment for Exparel, we stated that we considered Exparel to be a drug that functions as a surgical supply because it is indicated for the alleviation of postoperative pain. We also stated that we consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59345), we reiterated our position with regard to payment for Exparel, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. In addition, we have reviewed recently available literature with respect to Exparel, including a briefing document [94] submitted for the FDA Advisory Committee Meeting held February 14–15, 2018, by the manufacturer of Exparel that notes that ''Bupivacaine, the active pharmaceutical ingredient in Exparel, is a local anesthetic that has been used for infiltration/field block and peripheral nerve block for decades'' and that ''since its approval, Exparel has been used extensively, with an estimated 3.5 million patient exposures in the US.'' [95] On April 6, 2018, the FDA approved Exparel's new indication for use as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.[96] Therefore, we also stated in the CY 2019 OPPS/ASC proposed rule that, based on our review of currently available OPPS Medicare claims data and public information from the manufacturer of the drug, we did not believe that the OPPS packaging policy had discouraged the use of Exparel for either of the drug's indications. Accordingly, we continue to believe it is appropriate to package payment for Exparel as we do with other postsurgical pain management drugs when it is furnished in a hospital outpatient department. However, we invited public comments on whether separate payment would nonetheless further incentivize appropriate use of Exparel in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.

Comment: Several commenters requested that CMS pay separately for Exparel in the hospital outpatient setting. Some of these commenters noted that Exparel is used more frequently in this setting and the use of non-opioid pain management treatments should also be encouraged in the hospital outpatient department (HOPD). One commenter stated that since drug became packaged in 2015, utilization of the drug in the HOPD has remained flat while the opioid crisis has continued to worsen. The commenter suggested that to address the opioid crisis among Medicare beneficiaries, CMS should promote ''increased penetration of non-opioid therapies in the HOPD setting—or in other words, higher rates of usage of non-opioid treatments for the same number of surgical procedures.''

Response: This comment and other comments specific to packaging under the OPPS payment system are addressed in section II.A.3.b. of this final rule with comment period.

We also stated in the proposed rule that, although we found increases in utilization for Exparel when it is paid under the OPPS, we did notice different effects on Exparel utilization when examining the effects of our packaging policy under the ASC payment system. In particular, during the same 5-year period of CYs 2013 through 2017, the total number of units of Exparel used in the ASC setting decreased by 25 percent (from 98,160 total units to 73,595 total units) and the total number of claims reporting Exparel decreased by 16 percent (from 527 claims to 441 claims). In the ASC setting, after the pass-through payment period ended for Exparel at the end of CY 2014, the total number of units of Exparel used decreased by 70 percent (from 244,757 units to 73,595 units) between CYs 2015 and 2017. The total number of claims reporting Exparel also decreased during this time period by 62 percent (from 1,190 claims to 441 claims). However, there was an increase of 238 percent (from 98,160 total units to 331,348 total units) in the total number of units of Exparel used in the ASC setting during the time period of CYs 2013 and 2014 when the drug received pass-through payments, indicating that the payment rate of ASP+6 percent for Exparel may have an impact on its usage in the ASC setting. The total number of claims reporting Exparel also increased during this time period from 527 total claims to 1,540 total claims, an increase of 192 percent.

While several variables may contribute to this difference between utilization and claims reporting in the hospital outpatient department and the ASC setting, one potential explanation is that, in comparison to hospital outpatient departments, ASCs tend to provide specialized care and a more limited range of services. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may impact these providers more acutely than hospital outpatient departments, and therefore, ASCs may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result. Another possible contributing factor is that ASCs do not typically report packaged items and services and, accordingly, our analysis may be undercounting the number of Exparel units utilized in the ASC setting.

In light of the results of our evaluation of packaging policies under the OPPS and the ASC payment system, which showed decreased utilization for certain drugs that function as a supply in the ASC setting in comparison to the hospital outpatient department setting, as well as the Commission's recommendation to examine payment

[94] Food and Drug Administration, Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee Briefing Document (2018). Available at: *https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM596314.pdf.*

[95] Ibid, page 9.

[96] Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022496s009lbledt.pdf.*

policies for non-opioid pain management drugs that function as a supply, we stated in the proposed rule that we believe a change in how we pay for non-opioid pain management drugs that function as surgical supplies may be warranted. In particular, we believe it may be appropriate to pay separately for evidence-based non-opioid pain management drugs that function as a supply in a surgical procedure in the ASC setting to address the decreased utilization of these drugs and to encourage use of these types of drugs rather than prescription opioids. Therefore, we proposed in section XII.D.3. of the CY 2019 OPPS/ASC proposed rule (83 FR 37068 through 37071) to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019.

We have stated previously (82 FR 59250) that our packaging policies are designed to support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. The packaging policies established under the OPPS also typically apply when services are provided in the ASC setting, and the policies have the same strategic goals in both settings. While the CY 2019 proposal is a departure from our current ASC packaging policy for drugs (specifically, non-opioid pain management drugs) that function as a supply when used in a surgical procedure, we stated in the proposed rule we believe that the proposed change will incentivize the use of non-opioid pain management drugs and is responsive to the Commission's recommendation to examine payment policies for non-opioid pain management drugs that function as a supply, with the overall goal of combating the current opioid addiction crisis. As previously noted, a discussion of the CY 2019 proposal for payment of non-opioid pain management drugs in the ASC setting was presented in further detail in the proposed rule, and we include a further discussion of the final policy for CY 2019 below. However, we also stated in the CY 2019 OPPS/ASC proposed rule that we were interested in peer-reviewed evidence that demonstrates that non-opioid alternatives, such as Exparel, in the outpatient setting actually do lead to a decrease in prescription opioid use and addiction and invited public comments containing evidence that demonstrate whether and how such non-opioid alternatives affect prescription opioid use during or after an outpatient visit or procedure.

As noted above, for CY 2019, we proposed to pay separately at average sales price (ASP)+6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting. As described in section V.A.1. of the proposed rule, section 1847A of the Act establishes the ASP methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP) (82 FR 59337). As noted in section V.B.2.b. of the proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (82 FR 59350).

In the proposed rule (83 FR 37167), we did not propose a change to the packaging policy under the OPPS for CY 2019. However, we proposed to pay separately at ASP+6 percent for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in the ASC setting for CY 2019. Because the ASC payment rate also includes packaged payment for non-opioid pain management drugs, we intend to remove the packaged costs attributable to non-opioid pain management drugs—at this time, only Exparel qualifies—from the applicable OPPS rates prior to establishing the ASC rates in order to prevent potential overpayment of these procedures when separate payment is provided in the ASC setting.

Of the drugs that are currently packaged in the ASC setting, this policy would apply to Exparel. Exparel is the only non-opioid pain management drug that functions as a supply when used in a surgical procedure that is covered under Medicare Part B. While there are other non-opioid pain management drugs available that are also administered post-surgically, such as non-steroidal anti-inflammatory drugs (''NSAIDs''), Exparel is the currently the only drug used in the ASC setting that is both covered under Medicare Part B and policy packaged as a drug that functions as a supply in a surgical procedure. To the extent that other non-opioid drugs that function as surgical supplies come onto the U.S. market, we proposed that this policy would apply to them as well in CY 2019.

This proposal was also presented in section II.A.3.b. of the proposed rule for the OPPS. We proposed several conforming changes to the ASC regulation to implement this proposal. Specifically, at 42 CFR 416.164(a)(4), we proposed a change to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for a covered surgical procedure. Similarly, we proposed to add 42 CFR 416.164(b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as a covered ancillary service. Finally, we proposed a conforming change to 42 CFR 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

Comment: Several commenters supported the proposal to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as a supply in the ASC setting, such as Exparel, for CY 2019. These commenters believed that packaged payment for non-opioid alternatives presents a barrier to care and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic.

Other commenters, including MedPAC, did not support this proposal and stated that the policy was counter to the OPPS packaging policies created to encourage efficiencies and could set a precedent for unpackaging services. One commenter stated that Exparel is more costly, but not more effective than bupivacaine, a less costly non-opioid alternative. Other commenters expressed concerns that the proposal may have the unintended consequence of limiting access to opioid prescriptions for beneficiaries for whom an opioid prescription would be appropriate. The commenters noted that some non-opioid pain management treatments may pose other risks for patients and patient safety.

Response: We appreciate the commenters' input. We continue to believe that, under current circumstances, it is appropriate to pay separately for non-opioid pain management drugs that function as a supply in a surgical procedure in the

ASC setting where there is evidence that their use leads to decreased opioid use and/or addiction among Medicare beneficiaries following an outpatient visit or procedure. We believe this policy will encourage use of these types of drugs rather than prescription opioids. With regard to the comments that paying separately for these drugs could set a precedent for unpackaging other services, while we acknowledge that this policy is a departure from the current ASC packaging policy for drugs that function as a supply, we also believe that the limited scope of this policy, in terms of both the services included (evidence-based non-opioid pain management drugs) and the setting (ASCs) is sufficiently narrow and will not set an unwarranted precedent for the unpackaging of other OPPS or ASC services. We also do not believe that this policy will limit access to opioid prescriptions for beneficiaries for whom an opioid prescription would be appropriate. Exparel and other non-opioid pain management drugs packaged under the drugs that function as a supply policy are used to treat acute post-surgical pain and paying separately for these drugs under the ASC payment system will not prevent physicians from prescribing opioids for treating pain when appropriate. Also, we have a longstanding recognition that the decision on how to best treat a patient is a complex medical judgment made by the physician based on each individual beneficiary's unique clinical circumstances. With regard to concerns that some non-opioid pain management treatments pose other risks for patients and patient safety, the commenter did not identify any specific non-opioid pain management treatments in its comment. Exparel, the only drug to which the proposed policy applies, is currently being safely used in both the OPPS and ASC settings. This comment is also presented in section II.A.3.b of this final rule with comment period.

In addition, as noted in section XII.D.3. of the proposed rule, we sought comments on whether the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) as well as whether there are other non-opioid pain management alternatives that would have similar effects and may warrant separate payment. For example, we stated we were interested in identifying whether single post-surgical analgesic injections, such as Exparel, or other non-opioid drugs or devices that are used during an outpatient visit or procedure are associated with decreased opioid prescriptions and/or reduced cases of associated opioid addiction following such an outpatient visit or procedure. We also requested comments that provide evidence (such as published peer-reviewed literature) we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and, therefore, warrants separate payment under either or both the OPPS and the ASC payment system. We stated that any evidence demonstrating the reduction or avoidance of prescription opioids would be the criteria we use to determine whether separate payment is warranted for CY 2019. We also stated that, should evidence change over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.

Comment: With regard to whether the proposed policy would decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure and supportive evidence of these reductions, a commenter submitted studies that claimed that the use of Exparel by Medicare patients undergoing total knee replacement procedures reduced prescription opioid consumption by 90 percent compared to the control group measured at 48 hours post-surgery.[97] The commenter submitted additional studies claiming statistically significant reductions in opioid use with the use of Exparel for various surgeries including laparotomy, shoulder replacement, and breast reconstruction.

Several commenters identified other non-opioid pain management drugs that they believe decrease the dose, duration, and/or number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure (especially for beneficiaries at high-risk for opioid addiction) and may warrant separate payment for CY 2019. Several commenters submitted supporting studies which claimed that a non-opioid intrathecal infusion drug indicated for the management of severe chronic pain reduced opioid use in patients with chronic pain.

Other commenters representing hospitals, hospital associations, and clinical specialty organizations requested separate payment for IV acetaminophen, IV ibuprofen, and epidural steroid injections. In addition, one commenter, the manufacturers of a non-opioid analgesic containing bupivacaine hcl, but not currently approved by FDA, requested clarification regarding whether the proposal would also apply to this drug once it receives FDA approval. Several commenters requested separate payment for a drug which treats post-operative pain after cataract surgery, currently has drug pass-through status, and therefore is not packaged under the OPPS or ASC. The commenters requested that CMS explicitly state this drug will also be paid for separately in the ASC setting after pass-through status ends for the drug in 2020. Lastly, one commenter requested that a diagnostic drug that is not a non-opioid receive separate payment.

Response: We appreciate these comments. After reviewing the studies provided by the commenters, we continue to believe the separate payment is appropriate for Exparel in the ASC setting. At this time, we have not found compelling evidence for other non-opioid pain management drugs described above to warrant separate payment at this time. Also, with regard to the requests for CMS to confirm that the proposed policy would also apply in the future to certain non-opioid pain management drugs, we reiterate that the proposed policy is for CY 2019 and is applicable to non-opioid pain management drugs that that are currently packaged under the policy for drugs that function as a surgical supply when used in the ASC setting, which currently is only Exparel. To the extent that other non-opioid pain management drugs that function as a surgical supply become available in the U.S. market in CY 2019, this policy would also apply to those drugs.

As noted above, we stated in the proposed rule that we were interested in comments regarding other non-opioid treatments besides Exparel that might be affected by OPPS and ASC packaging policies, including alternative, non-opioid pain treatments, such as devices or therapy services that are not currently separable payable. We stated that we were specifically interested in comments regarding whether CMS should consider separate payment for items and services for which payment is currently packaged under the OPPS and the ASC payment system that are effective non-opioid alternatives as well as evidence that demonstrates such items and services lead to a decrease in prescription opioid use and/or

[97] Michael A. Mont et al., Local Infiltration Analgesia With Liposomal Bupivacaine Improves Pain Scores and Reduces Opioid Use After Total Knee Arthroplasty: Results of a Randomized Controlled Trial. J. of Arthroplasty (2018).

addiction during or after an outpatient visit or procedure in order to determine whether separate payment may be warranted. As previously stated, we intended to examine the evidence submitted to determine whether to adopt a final policy in this final rule with comment period that incentivizes use of non-opioid alternative items and services that have evidence to demonstrate an associated decrease in prescription opioid use and/or addiction following an outpatient visit or procedure. Some examples of evidence that may be relevant could include an indication on the product's FDA label or studies published in peer-reviewed literature that such product aids in the management of acute or chronic pain and is an evidence-based non-opioid alternative for acute and/or chronic pain management. We indicated in the proposed rule that we also were interested in evidence relating to products that have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. We stated this could include, for example, spinal cord stimulators used to treat chronic pain such as the devices described by HCPCS codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), and C1767 (Generator, neurostimulator (implantable), nonrechargeable) which are primarily assigned to APCs 5463 and 5464 (Levels 3 and 4 Neurostimulator and Related Procedures) with proposed CY 2019 payment rates of $18,718 and $27,662, respectively, that have received pass-through payment status as well as other similar devices.

Currently, all devices are packaged under the OPPS and the ASC payment system unless they have pass-through payment status. However, we stated in the proposed rule that, in light of the Commission's recommendation to review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, we were interested in comments from stakeholders regarding whether, similar to the goals of the proposed payment policy for non-opioid pain management drugs that function as a supply when used in a surgical procedure, a policy of providing separate payment (rather than packaged payment) for these products, indefinitely or for a specified period of time, would also incentivize the use of alternative non-opioid pain management treatments and improve access to non-opioid alternatives, particularly for innovative and low-volume items and services.

We also stated that we were interested in comments regarding whether we should provide separate payment for non-opioid pain management treatments or products using a mechanism such as an equitable payment adjustment under our authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments. For example, we stated in the proposed rule that we were considering whether an equitable payment adjustment in the form of an add-on payment for APCs that use a non-opioid pain management drug, device, or service would be appropriate. We indicated that, to the extent that commenters provided evidence to support this approach, we would consider adopting a final policy in this final rule with comment period, which could include regulatory changes that would allow for an exception to the packaging of certain nonpass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions and/or addictions during or after an outpatient visit or procedure to effectuate such change.

Comment: Several commenters stated that separate payment for spinal cord stimulators (SCS) was also warranted because these devices provide an alternative treatment option to opioids for patients with chronic, leg or back pain. One commenter provided supporting studies which claimed that patients treated with their device reported a statistically significant average decrease in opioid use compared to the control group.[98] This commenter also submitted data that showed a decline in the mean daily dosage of opioid medication taken and that fewer patients were relying on opioids at all to manage their pain when they used the manufacturer's device.[99] Another commenter stated that there are few peer-reviewed studies that evaluate opioid elimination and/or reduction following SCS and that there is a need for more population based research with opioid reduction or elimination as a study endpoint. However, this commenter believed that current studies suggest that opioid use may be reduced following SCS therapy.

Other commenters requested separate payments for various non-opioid pain management treatments such as: Continuous nerve blocks (including a disposable elastomeric pump that delivers non-opioid local anesthetic to a surgical site or nerve); cooled thermal radiofrequency ablation for non-surgical, chronic nerve pain; and physical therapy services. These commenters also stated that while ''certainly not a solution to the opioid epidemic, unpackaging appropriate non-opioid therapies, like Exparel, is a low-cost tactic that could change long-standing practice patterns without major negative consequences.'' One commenter suggested that Medicare consider separate payment for Polar ice devices for post-operative pain relief after knee procedures. The commenter also noted that therapeutic massage, topically applied THC oil, acupuncture, and dry needling procedures are very effective therapies for relief of both post-operative pain and long-term and chronic pain.

Commenters suggested various mechanisms through which separate payment or a higher paying APC assignment for the primary service could be made. Commenters offered reports, studies and anecdotal evidence to support why the items or services about which the commenters believed offered alternatives to or reduction of the need for opioid prescriptions.

Response: We appreciate the thoughtful response to our solicitation for comments on this topic. We plan to take these suggestions into consideration for future rulemaking. We agree that providing incentives to avoid and/or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. We note that some of the items and services mentioned by commenters are not covered by Medicare and we do not intend to establish payment for noncovered items and services. We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC

[98] Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Brown LL, Yearwood TL, Bundschu R, Burton AW, Yang T, Benyamin R, Burgher AH. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: The SENZA–RCT randomized controlled trial, ANESTHESIOLOGY. 2015 Oct;123(4):851–60.

[99] Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. PAIN MED. 2014 Mar; 15(3):347–54.

payment system that will encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or addictions during or after an outpatient visit or procedure.

Comment: One commenter suggested that CMS provide separate payment for HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour) in the hospital outpatient department and the ASC settings following a post-surgery procedure. This commenter explained that if a patient needs additional pain relief three to five days post-surgery, a facility cannot receive payment for providing a replacement disposable drug delivery system HCPCS code A4306 unless the entire continuous nerve block procedure is performed. This commenter believed that CMS should allow for HCPCS code A4306 to be dispensed to the patient as long as the patient is in pain, the pump is empty, and the delivery catheters are still in place. The commenter believed that the ASC payment system should incentivize the continued use of non-opioid alternatives when needed. Several commenters stated that CMS should use an equitable payment adjustment under its authority at section 1833(t)(2)(E) of the Act to establish add-on payments for packaged devices used as non-opioid alternatives.

Response: We appreciate the commenters' suggestions. We acknowledge that use of these items may help in the reduction of opioid use post operatively. However, we note that packaged payment of such item does not prevent the use of these items. We remind readers that payment for packaged items is included in the payment for the primary service. We share the commenter's concern about the need to reduce opioid use and will take the commenter's suggestion into consideration for future rulemaking. After reviewing the non-opioid pain management alternatives suggested by the commenters as well as the studies and other data provided to support the request for separate payment, we have not determined that separate payment is warranted at this time for any of the non-opioid pain management alternatives discussed above.

We also invited comments on whether a reorganization of the APC structure for procedures involving non-opioid products or establishing more granular APC groupings for specific procedure and device combinations to ensure that the payment rate for such services is aligned with the resources associated with procedures involving specific devices would better achieve our goal of incentivizing increased use of non-opioid alternatives, with the aim of reducing opioid use and subsequent addiction. For example, we stated we would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services and decrease or eliminate the need for prescription opioids. In addition, given the general desire to encourage provider efficiency through creating larger bundles of care and packaging items and services that are integral, ancillary, supportive, dependent, or adjunctive to a primary service, we also invited comments on how such alternative payment structures would continue to balance the goals of incentivizing provider efficiencies with encouraging the use of non-opioid alternatives to pain management.

Furthermore, because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, we stated that we were interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy. We also stated that the implications of incentivizing use of non-opioid pain management drugs available for postsurgical acute pain relief during or after an outpatient visit or procedure are of interest. The goal is to encourage appropriate use of such non-opioid alternatives. As previously stated, this comment solicitation is also discussed in section XII.D.3. of this final rule with comment period.

Comment: One commenter suggested that CMS restructure the two-level Nerve Procedure APCs (5431 and 5432) to provide more payment granularity for the procedures included in the APCs by creating a third level.

Response: We refer readers to section III.D.6. of this final rule with comment period for a discussion of this comment. We believe that the current two-level APCs for the Nerve Procedures provide an appropriate distinction between the resource costs at each level and provide clinical homogeneity. We will continue to review this APC structure, to determine if additional granularity is necessary for this APC family in future rulemaking. In addition, we believe that more analysis of such groupings is necessary before adopting such change.

In addition, we invited the public to submit ideas on regulatory, subregulatory, policy, practice, and procedural changes to help prevent opioid use disorders and improve access to treatment under the Medicare program. We stated that we were interested in identifying barriers that may inhibit access to non-opioid alternatives for pain treatment and management or access to opioid use disorder treatment, including those barriers related to payment methodologies or coverage. In addition, consistent with our ''Patients Over Paperwork'' Initiative, we stated that we were interested in suggestions to improve existing requirements in order to more effectively address the opioid epidemic.

Comment: Several commenters offered views regarding payment barriers that may inhibit access to non-opioid pain management treatments which have been previously discussed throughout this section. With regard to barriers related to payment methodologies or coverage, some commenters suggested that CMS support multi-modal pain management and enhanced recovery after surgery (ERAS) and encourage patient access to certified registered nurse anesthetist (CRNA) pain management. One commenter also suggested that CMS reduce cost sharing and eliminate the need for prior authorization for non-opioid pain management strategies.

Response: We appreciate the various, insightful comments received from stakeholders regarding barriers that may inhibit access to non-opioid alternatives for pain treatment and management in order to more effectively address the opioid epidemic. Many of these comments have been previously addressed throughout this section.

After consideration of the public comments that we received, we are finalizing the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019 as proposed. We also are finalizing our conforming changes to the ASC regulation as proposed. Specifically, we are finalizing our proposed conforming changes to 42 CFR 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We also are adding a new paragraph (6) to 42 CFR 416.164(b) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, we are

finalizing our proposed change to 42 CFR 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

We will continue to analyze this issue on access to non-opioid alternatives in the OPPS and ASC settings as we implement section 6082 of the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271) enacted on October 24, 2018. This policy is also discussed in section II.A.3.b. of this final rule with comment period.

E. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in 42 CFR 416.195.

1. NTIOL Application CycleOur process for reviewing applications to establish new classes of NTIOLs is as follows:

• Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

• We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

• In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments;

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2019

We did not receive any requests for review to establish a new NTIOL class for CY 2019 by March 1, 2018, the due date published in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59416).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2019.

4. Announcement of CY 2020 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLs

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2020, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5:00 p.m. EST, on March 1, 2019. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators used in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). In the CY 2017 OPPS/ASC final rule with comment period, we responded to public comments and finalized the ASC treatment of all codes that were labeled with comment indicator ''NP'' in Addenda AA and BB to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment

indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79748 through 79749), for CY 2017 and subsequent years, we finalized our policy to continue using the current comment indicators of ''NP'' and ''CH''.

2. ASC Payment and Comment Indicators

In the CY 2019 OPPS/ASC proposed rule, for CY 2019, there were proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2018 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2019 compared to the CY 2018 descriptors that were included in ASC Addenda AA and BB to the proposed rule are labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of the proposed rule. Proposed comment indicator ''NP'' means a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year; and denotes that comments will be accepted on the proposed ASC payment indicator for the new code.

In the proposed rule, we stated that we would respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in this CY 2019 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 to the proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2019 update.

We did not receive any public comments on the ASC payment and comment indicators. Therefore, we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this final rule with comment period (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for the CY 2019 update.

G. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; 42 CFR 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this final rule with comment period), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*.) In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66937), we finalized a 1-year transition policy that we applied in CY 2015 for all ASCs that experienced any decrease in their actual wage index exclusively due to the implementation of the new OMB delineations. This transition does not apply in CY 2019.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, ''[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.'' (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*.)

OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions.

In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. We note that we did not have sufficient time to include this change in the computation of the proposed FY 2019 IPPS wage index. We stated that this new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of ASCs located in this new CBSA. In the CY 2019 OPPS/ASC proposed rule (83 FR 37075), we provided an estimate (shown below) of this new area's wage index based on the average hourly wages for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index (described in section III.B. of the preamble of the FY 2019 IPPS/LTCH PPS proposed rule). Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 was calculated using the average hourly wage data for one provider (provider 130002).

	Estimated Unadjusted Wage Index for New CBSA 46300	**Estimated Occupational Mix Adjusted Wage Index for New CBSA 46300**
Proposed National Average Hourly Wage	42.990625267	42.948428861
Estimated CBSA Average Hourly Wage	35.833564813	38.127590025
Estimated Wage Index	0.8335	0.8878

Other than the previously described wage index, for CY 2019, the final CY 2019 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01 and 17–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan

divisions where applicable) that are contiguous to the area with no wage index.)

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2019 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). In the CY 2019 OPPS/ASC proposed rule (83 FR 37171), consistent with our established policy, we proposed to scale the CY 2019 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2017, we proposed to compare the total payment using the CY 2018 ASC relative payment weights with the total payment using the CY 2019 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2018 and CY 2019. We proposed to use the ratio of CY 2018 to CY 2019 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2019. The proposed CY 2019 ASC weight scalar was 0.8854 and scaling would apply to the ASC relative payment weights of the covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of the proposed rule, we had available 98 percent of CY 2017 ASC claims data.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2017 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2017 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the proposed rule, is posted on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2019, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2017 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2019 ASC wage indexes. Specifically, holding CY 2017 ASC utilization, service-mix, and the proposed CY 2019 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2018 ASC wage indexes (which would fully reflect the new OMB delineations) and the total adjusted payment using the proposed CY 2019 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2018 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2019 ASC wage indexes and applied the resulting ratio of 1.0003 (the proposed CY 2019 ASC wage index budget neutrality adjustment) to the CY 2018 ASC conversion factor to calculate the proposed CY 2019 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at 42 CFR 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2018 OPPS/ASC rulemaking (82 FR 33668 through 33670; 59422 through 59424), we solicited and discussed comments regarding our current policy, codified at 42 CFR 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years. In the CY 2018 OPPS/ASC final rule with comment period, we noted that in 2008 facilities paid under the ASC payment system received approximately 65 percent of the payment that hospitals paid under the OPPS received for an average service. The differential between ASC facility payment and OPPS provider payment has continued to increase since 2008, and by 2017, facilities paid under the ASC payment system received approximately 56 percent of the payment that hospitals paid under the OPPS received for an average service. At the same time, indicators of ASC payment adequacy, such as capacity and supply of providers and providers' access to capital, suggest that Medicare beneficiaries have adequate access to ASC services.[100]

The Administration recognizes the value that ASCs may bring to the Medicare Program that results in the delivery of efficient, high-quality care to beneficiaries at a lower cost. The Administration is promoting greater

[100] MedPAC. Report to the Congress: March 2018.

price transparency across all of Medicare's payment systems. Both beneficiaries and the Medicare Program benefit from reduced expenditures when a beneficiary's clinical needs allow for a procedure to be performed in lower cost settings, such as ASCs relative to hospital outpatient departments.[101]

As articulated in the FY 2019 President's Budget, the Administration supports payment reforms that base payment on patient characteristics rather than the site of care. To that end, we are exploring ways to align payments with the costs of care and to incentivize use of the most efficient and clinically appropriate sites of care including hospital outpatient departments, ASCs, and physician offices, to the extent feasible, in future rulemaking. In the near term, however, there is concern by some stakeholders that the differential between payment updates for HOPDs and ASCs is resulting in inefficient and unnecessary shifts of care to the hospital outpatient setting and away from ASCs. We are concerned about the potential unintended consequences of using the CPI–U to update payments for ASCs, such as consolidation of ASCs or fewer physician-owned ASCs, which may contribute to higher prices; stagnation in number of ASC facilities and number of multispecialty ASC facilities; and payments being misaligned with the cost of treatment for complex patients.

We recognize prior public commenters' belief that ASCs may incur some of the same costs that hospitals incur, which may be better reflected in the hospital market basket update than the CPI–U. Nevertheless, we recognize also that ASCs are among the only health care facilities in Medicare that do not submit cost information and therefore their rates are not updated based on a related market basket. We do not believe that the ASC cost structure is identical to the hospital cost structure for a few reasons (these differences are illustrative and not exhaustive). First, the majority of ASCs are single specialty (61 percent based on 2016 data), whereas hospitals provide a wider variety of services, and also provide inpatient care and room and board. Second, the vast majority of ASCs are for-profit and located in urban areas, whereas hospital ownership is varied and hospitals are located in more geographically diverse locations. Third, compliance with certain laws, such as the Emergency Medical Treatment and Labor Act (EMTALA), apply to hospitals and do not apply to ASCs. These differences illustrate why there is reason to believe there is a measure of misalignment between the HOPD and ASC cost structure, and should be considered when assessing the suitability of using the hospital market basket as a better proxy for ASC costs than the CPI–U.

According to commenters on the CY 2018 OPPS/ASC proposed rule, only 8.5 percent of the CPI–U inputs are related to health care, and even those inputs are based on a consumer's experience purchasing health care items, rather than a provider's experience purchasing the items necessary to furnish a health care service, and do not measure whether a facility's costs increase, such as the cost of purchasing supplies and equipment or personnel labor costs.

We also acknowledge prior public commenters' concern that the disparity in payments between the OPPS and the ASC payment system may reduce the migration of services from the HOPD setting to the less costly ASC setting. For example, one study looked at the impact of the difference in facility fees paid to ASCs versus hospital outpatient departments on ASC growth using a fixed effects model.[102] The study found results indicating that, as ASC payments increase, patients are more likely to undergo outpatient procedures in an ASC than they are in a hospital. Another study found that the opening of an ASC in a hospital service area resulted in a decline in hospital-based outpatient surgery without increasing mortality or admission.[103] In markets where facilities opened, procedure growth at ASCs was greater than the decline in outpatient surgery use at their respective hospitals.

If a migration of services from the hospital setting to ASCs occurred, it may potentially yield savings to the Medicare program and beneficiaries if the savings from the migration of services net of any increases in total volume of services does not exceed the cost of a higher rate update factor. ASC payment rates would still generally be significantly less than under the OPPS.

To the extent that it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice. While there are several factors that contribute to the divergence in payment between the two systems (which were identified in the comment solicitation on ASC payment reform in the CY 2018 OPPS/ASC rulemaking), such as different distribution of costs between hospitals and ASCs and different ratesetting methodologies between the OPPS and the ASC payment system, we believe that an alternative update factor could stabilize the differential between the OPPS payment and the ASC payment, to the extent that the CPI–U has been lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate (82 FR 59422 through 59424). In addition, we note that there are many services that can safely be performed in either the hospital setting or the ASC setting and a common rate update factor recognizes that the two provider types often compete for the same patients though patient acuity is likely higher in hospitals.

Therefore, we believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care. However, because physicians have a financial interest in ASCs, higher payments could also lead to greater utilization of services.[104] At the same time, we are cognizant of concerns that Medicare does not currently collect cost data from ASCs, which makes it difficult to assess payment adequacy in the same way that it is assessed for hospitals, to validate alignment between ASC and hospital cost structure, or to establish an ASC-specific market basket. Accordingly, until we have information on the ASC cost structure, we would like to balance our desire to promote migration of services away from the HOPD to ASCs where clinically appropriate with our desire to minimize increases in beneficiary out-of-pocket costs. In the CY 2019 OPPS/ASC proposed rule (83 FR 37173 through 37175), therefore, as described in more specific detail below, we proposed to apply a hospital market basket update to

[101] *Medicare Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates,* Department of Health and Human Services, Office of Inspector General, April 2014.

[102] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. *Journal of Health Economics,*Volume 57, January 2018.

[103] Hollenbeck BK, Dunn RL, et. al. Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery. HSR: Health Services Research. 50:5. October 2015.

[104] Munnich EL, Parente ST. Returns to Specialization: Evidence from the Outpatient Surgery Market. *Journal of Health Economics,* Volume 57, January 2018.

ASCs for an interim period of 5 years but sought comments on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs. We noted that the hospital market basket is collected under OMB Control No. 0938–0050 and the information collected through hospital cost reports is used, in part, to inform the calculation of the hospital market basket.

We proposed that the hospital market basket update applied to ASC payment rates would be derived using the same hospital inpatient market basket percentage increase that we proposed to use to derive the OPD fee increase factor as described in section II.B. of the CY 2019 OPPS/ASC proposed rule and would be adjusted for multifactor productivity. We proposed this payment update methodology for a 5-year period, during which we proposed to assess whether there is a migration of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences (for example, an unnecessary increase in the overall volume of services or beneficiaries' out-of-pocket costs). We believed that 5 years would be an appropriate number of years to assess changes in the migration of services, as it should provide us enough time to confirm that trends in the data are consistent over time. In the proposed rule, we welcomed comment on whether implementing the hospital market basket update for a different number of years might be more appropriate.

In the proposed rule, we stated that we were interested in commenter feedback on additional ways we can evaluate the impacts of this payment change over the 5-year period. For example, we welcomed input on how we should delineate between changes in the volume of a particular service due to the higher update, versus changes in the volume of a service due to changes in enrollment, patient acuity, or utilization, and what would be an appropriate interval to measure such migration of services.

During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. As previously mentioned, in response to the comment solicitation in the CY 2018 OPPS/ASC proposed rule, stakeholders indicated a willingness to work with CMS to collect cost information in the least burdensome manner (82 FR 59422 through 59424).

Therefore, for CY 2019 through 2023, in response to stakeholder concerns described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59420 through 59421) that ASCs may incur some of the same costs that hospitals incur and that are better reflected in the hospital market basket update than the CPI–U, and including the concern that the payment differentials between the different settings of care due to the use of the CPI–U may stagnate the migration of services from hospitals to the ASC setting, even though those services can be safely performed in ASCs, we proposed to update ASC payment rates using the hospital market basket and to revise our regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor, to reflect this proposal. In addition, we requested comments and evidence to assess whether the hospital market basket is an appropriate proxy for ASC costs. Under this proposal, for CY 2019, we proposed to use the FY 2019 hospital market basket update as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381). This proposed update to ASC payment rates was derived using the same hospital inpatient market basket percentage increase that we proposed to use to derive the OPD fee increase factor as described in section II.B. of the CY 2019 OPPS/ASC proposed rule. We also sought comments on an alternative proposal to maintain using the CPI–U for the annual ASC payment update while collecting evidence to justify a different payment update, or adopting the new proposed payment update based on the hospital market basket permanently. We requested comments on what type of evidence should be used to justify a different payment update and how CMS should go about collecting that information in the least burdensome way possible.

Section 1833(t)(3)(G)(v) of the Act applies an additional adjustment of 0.75 for CY 2019 to hospitals. We noted that such adjustment was authorized by the Affordable Care Act and that, while the Affordable Care Act authorized a productivity adjustment for ASCs (as it did for hospitals), it expressly did not authorize the ''additional adjustment'' that was mandated for hospitals. The additional adjustment is separate and distinct from the productivity adjustment that already applies to both hospitals and ASCs and there does not appear to be a correlation between the productivity adjustment and the additional adjustment. Further, application of the additional adjustment may be contrary to the goals we have articulated that led us to propose to apply the hospital market basket to the ASC payment system in the first place; that is, we believe that proposing to apply the hospital market basket to ASC rates may encourage the migration of services from the hospital setting to the ASC setting. However, if we had proposed to apply the additional adjustment, the ASC rate update would have been 1.25 percent, instead of the proposed 2.0 percent. The 1.25 percent was lower than applying the CPI–U rate update factor, which at the time of the CY 2019 OPPS/ASC proposed rule would have been 1.3 percent for CY 2019. This lower update would appear contrary to the goals set forth earlier in this section. However, we sought comment on whether applying this additional adjustment may nonetheless be appropriate.

While we expect this policy will increase spending, by both the government and beneficiaries, relative to the current update factor over the 5-year period, as previously stated, we also believe that the proposal could encourage the migration of services that are currently performed in the hospital outpatient setting to the ASC setting, which could result in savings to beneficiaries and the Medicare program. We believe that it is important to maximize patient choice to obtain services at a lower cost to the extent feasible. We believe also that without cost data from ASCs to examine their cost structure and adequacy of payment, we lack key data that may help inform the development of payment policies that are based on patients' clinical needs rather than the site of care.

In the proposed rule, we stated that, if, after review of all comments and all available evidence, we chose to finalize this proposal, we would continue to monitor site-of-service shifts for the duration of this policy to determine if services move safely to lower cost settings and to explore collecting additional data that may help inform further development of the ASC payment system. We proposed to continue to use the adjusted hospital market basket update through CY 2023 (for 5 years total). We proposed that we intend to reassess whether application of the hospital market basket update to ASC rates has provided more patient choice to obtain services at a lower cost beginning with the CY 2024 rulemaking period, or sooner if appropriate.

Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new clause (v), which requires that any annual update under the ASC payment system for the year,

after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, effective with the calendar year beginning January 1, 2011. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). Clause (iv) of section 1833(i)(2)(D) of the Act authorizes the Secretary to provide for a reduction in any annual update for failure to report on quality measures. Clause (v) of section 1833(i)(2)(D) of the Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized a policy that ASCs begin submitting data on quality measures for services beginning on October 1, 2012 for the CY 2014 payment determination under the ASC Quality Reporting (ASCQR) Program. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), we finalized a methodology to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for the CY 2014 payment determination and subsequent years. The application of the 2.0 percentage point reduction to the annual update factor, which we proposed to be the hospital market basket update, may result in the update to the ASC payment system being less than zero for a year for ASCs that fail to meet the ASCQR Program requirements. We amended §§ 416.160(a)(1) and 416.171 to reflect these policies.

In prior years, in accordance with section 1833(i)(2)(C)(i) of the Act, before applying the MFP adjustment, the Secretary first determined the ''percentage increase'' in the CPI–U, which we interpreted cannot be a negative percentage. Thus, in the instance where the percentage change in the CPI–U for a year was negative, we would hold the CPI–U update factor for the ASC payment system to zero (75 FR 72062). Consistent with past practice, in the instance where the percentage change in the hospital market basket for a year is negative, we proposed to hold the hospital market basket update factor for the ASC payment system to zero. For the CY 2014 payment determination and subsequent years, under section 1833(i)(2)(D)(iv) of the Act, we would reduce the annual update by 2.0 percentage points for an ASC that fails to submit quality information under the policies established by the Secretary in accordance with section 1833(i)(7) of the Act. Section 1833(i)(2)(D)(v) of the Act, as added by section 3401(k) of the Affordable Care Act, requires that the Secretary reduce the annual update factor, after application of any quality reporting reduction, by the MFP adjustment, and states that application of the MFP adjustment to the annual update factor after application of any quality reporting reduction may result in the update being less than zero for a year. If the application of the MFP adjustment to the annual update factor after application of any quality reporting reduction would result in an MFP-adjusted update factor that is less than zero, the resulting update to the ASC payment rates would be negative and payments would decrease relative to the prior year. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062 through 72064) for examples of how the MFP adjustment is applied to the ASC payment system.

For the CY 2019 OPPS/ASC proposed rule, the hospital market basket update for CY 2019 was projected to be 2.8 percent, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20381), based on IHS Global Inc.'s (IGI's) 2017 fourth quarter forecast with historical data through the third quarter of 2017. For this final rule with comment period, as published in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41395), based on IGI's 2018 second quarter forecast with historical data through the first quarter of 2018, the hospital market basket update for CY 2019 is 2.9 percent.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). For the CY 2019 OPPS/ASC proposed rule, the proposed MFP adjustment for CY 2019 was projected to be 0.8 percentage point, as published in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20382) based on IGI's 2017 fourth quarter forecast. For this final rule with comment period, as published in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41395) based on IGI's 2018 second quarter forecast, the final MFP adjustment for CY 2019 is 0.8 percentage point.

We note that the update factor for CY 2019 under the current policy, which is to increase the payment amounts by the percentage increase in the CPI–U, U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, is currently projected to be 2.6 percent (based on IGI's third quarter 2018 forecast). The MFP adjustment that aligns with this payment update under current policy (ending with the midpoint of the year involved) is 0.8 percentage point, resulting in an update amount under the current policy of 1.8 percent (CPI–U of 2.6 percent less MFP adjustment of 0.8 percentage point).

For CY 2019, we proposed to utilize the hospital market basket update of 2.8 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.0 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2019 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We proposed to utilize the hospital market basket update of 2.8 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.8 percentage point MFP adjustment. Therefore, we proposed to apply a 0.0 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data were subsequently available (for example, a more recent estimate of the hospital market basket update and MFP), we would use such data, if appropriate, to determine the CY 2019 ASC update for the final rule with comment period.

For CY 2019, we proposed to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital market basket update factor of 2.0 percent discussed above, which resulted in a proposed CY 2019 ASC conversion

factor of $46.500 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.0 percent discussed above, which resulted in a proposed CY 2019 ASC conversion factor of $45.589.

Comment: The majority of commenters supported the proposal to update ASC payment rates using the hospital market basket update. A number of commenters suggested that the CPI–U is not a suitable inflation index to update ASC payments because it does not accurately represent the costs of ASCs or health care facilities, broadly. One commenter noted that only 8 percent of the CPI–U index is comprised of health care-related items and no other Medicare payment system utilizes the CPI–U as a provider inflation-metric as many payment systems for other providers utilize a provider-specific market basket index. The commenter also noted that, while the hospital market basket update is the most appropriate update factor to apply to ASC payment system rates, alternative update factors (for example, the Medicare Economic Index) would have been preferable to the CPI–U.

Other commenters in support of the proposal suggested that ASCs may incur some of the same costs that hospitals incur. In addition, commenters suggested that utilizing the hospital market basket update as the update mechanism would promote site neutrality and help restore relativity of average ASC payment rates to average HOPD payment rates. Some commenters recommended that CMS establish the hospital market basket update permanently as the ASC rate update mechanism rather than on an interim basis over 5 years.

Commenters also supported the proposal to not apply the additional adjustment of 0.75 percentage points that applies to hospitals under section 1833(t)(3)(G)(v) of the Act.

However, some commenters, including MedPAC, disagreed with the proposal and recommended collecting cost data from ASCs to inform an ASC-specific market basket index for updating payment rates under the ASC payment system. MedPAC noted that ASCs are fully capable of submitting cost report data, similar to other providers, such as ESRD facilities, hospices, and home health agencies. In addition, MedPAC suggested that, to minimize burden on ASCs and CMS, CMS could require all ASCs to submit streamlined cost reports or require a random sample of ASCs to submit cost data.

Response: We appreciate the commenters' support. We recognize the commenters' belief that ASCs may incur some of the same costs that hospitals incur, which may be better reflected in the hospital market basket update than the CPI–U. We also are aware that only a relatively small percentage of the CPI–U inputs are related to health care, and even those inputs are based on a consumer's experience purchasing health care items, rather than a provider's experience purchasing the items necessary to furnish a health care service, and do not directly relate to a facility's costs, such as the cost of purchasing supplies and equipment or labor costs. We also acknowledge commenters' concern that the disparity in payments between the OPPS and the ASC payment system may reduce the migration of services from the HOPD setting to the less costly ASC setting. We believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care. We believe that it is important to encourage such migration of services and that this policy would give physicians and patients greater choice in selecting the best care setting.

In addition, we acknowledge commenters recommendations regarding the collection of ASC cost data to inform an ASC-specific market basket index for updating payment rates under the ASC payment system. We appreciate these comments and will take these comments into consideration in future policy development.

Comment: Many commenters recommended that CMS discontinue ''rescaling'' the ASC relative weights and, instead, apply the OPPS relative weights as developed under the standard ratesetting methodology. The commenters argued that the weight scalar distorts ASC payments and further increases the payment differential between HOPDs and ASCs.

Response: We note that applying the weight scalar in calculation of ASC payment rates, which for this final rule with comment period is 0.8792, ensures that the ASC payment system remains budget neutral. For a detailed discussion on why we apply a budget neutrality adjustment to the ASC ratesetting methodology, we refer readers to the August 2, 2008 final rule (72 FR 42531 through 42533).

After consideration of the public comments we received, we are finalizing our proposal to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we are finalizing our proposal to revise our regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor.

Therefore, as proposed, to determine the CY 2019 ASC update for this final rule with comment period, we are incorporating a more recent estimate of the hospital market basket update and the MFP adjustment. For this CY 2019 OPPS/ASC final rule with comment period, as published in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41395), based on IGI's 2018 second quarter forecast with historical data through the first quarter of 2018, the MFP-adjusted hospital market basket update for CY 2019 is 2.1 percent (that is, the hospital market basket increase of 2.9 percent minus the MFP adjustment of 0.8 percentage point). Therefore, we are finalizing the application of a 2.1 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2019 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We are finalizing to utilize the hospital market basket update of 2.9 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.8 percentage point MFP adjustment. Therefore, we are applying a 0.1 percent MFP-adjusted hospital market basket update factor to the CY 2018 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2019, we are adjusting the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted hospital market basket update factor of 2.1 percent

discussed above, which results in a CY 2019 ASC conversion factor of $46.551 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.1 percent discussed above, which results in a CY 2019 ASC conversion factor of $45.639.

3. Display of CY 2019 ASC Payment Rates

Addenda AA and BB to this final rule with comment period (which are available on the CMS website) display the final updated ASC payment rates for CY 2019 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the final rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the final PFS rates that will be effective January 1, 2019. For a discussion of the PFS rates, we refer readers to the CY 2019 PFS final rule with comment period.

The final payment rates included in these addenda reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the final CY 2019 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2018. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

The values displayed in the column titled ''Final CY 2019 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2019. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs.

To derive the final CY 2019 payment rate displayed in the ''Final CY 2019 Payment Rate'' column, each ASC payment weight in the ''Final CY 2019 Payment Weight'' column was multiplied by the final CY 2019 conversion factor of $46.551. The final conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment (as discussed in section XII.G.2.b. of this final rule with comment period).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2019 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2019 Payment'' column displays the final CY 2019 national unadjusted ASC payment rates for all items and services. The final CY 2019 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in October 2018.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2019.

XIII. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program (formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program). In addition to the Hospital IQR and Hospital OQR Programs, CMS has implemented quality reporting programs as well as value-based purchasing programs for other care settings.

We refer readers to section I.A.2. of this final rule with comment period where we discuss our new Meaningful Measures Initiative and our approach in evaluating quality program measures.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2018 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; and 81 FR 79753 through 79797; 82 FR 59424 through 59445). We have also codified certain requirements under the Hospital OQR Program at 42 CFR 419.46.

4. Meaningful Measures Initiative

In the CY 2019 OPPS/ASC proposed rule, we proposed a number of new policies for the Hospital OQR Program (83 FR 37179). We developed these proposals after conducting an overall review of the program under our new

Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of this final rule with comment period. The proposals reflect our efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). These proposals also reflect our efforts to improve the usefulness of the data that we publicly report in the Hospital OQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow hospitals and patients to continue to obtain meaningful information about HOPD performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to hospitals associated with participating in this program do not outweigh the benefits of improving beneficiary care.

B. Hospital OQR Program Quality Measures

1. Considerations in the Selection of Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. In the CY 2019 OPPS/ASC proposed rule (83 FR 37176) we did not propose any changes to these policies.

2. Accounting for Social Risk Factors in the Hospital OQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425 through 59427), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[105] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[106] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59425), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[107] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.* The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[108] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based purchasing program measure selection, domain

[105] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities;* or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[106] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[107] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[108] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across health care settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital IQR Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

While we did not specifically request comment on social risk factors in the CY 2019 proposed rule, we received several comments with respect to social risk factors. We thank commenters for sharing their views and their willingness to support the efforts of CMS and NQF on this important issue. We take this feedback seriously and will continue to review social risk factors on an on-going and continuous basis. In addition, we both welcome and appreciate stakeholder feedback as we continue our work on these issues.

3. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). Thus, quality measures adopted in a previous year's rulemaking are retained in the Hospital OQR Program for use in subsequent years unless otherwise specified. We refer readers to that final rule with comment period for more information. In the CY 2019 OPPS/ASC proposed rule (83 FR 37177), we did not propose any changes to our retention policy; however, we proposed to codify this policy at 42 CFR 419.46(h)(1).

We did not receive any public comments and are finalizing our proposal to codify at 42 CFR 419.46(h)(1) our policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets as proposed.

4. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60315), we finalized a process to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns.[109] In the CY 2019 OPPS/ASC proposed rule (83 FR 37177), we did not propose any changes to this policy; however, we proposed to codify this policy at 42 CFR 419.46(h)(3). We refer readers to section XIII.B.4.a. of this final rule with comment period for more details.

We did not receive any public comments and are finalizing our proposal to codify at 42 CFR 419.46(h)(3) our policy to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns as proposed.

a. Considerations in Removing Quality Measures From the Hospital OQR Program

(1) Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for immediate retirement, which we later termed ''removal,'' of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raise patient safety concerns.[110] In the CY 2019 OPPS/ASC proposed rule (83 FR 37177), we did not propose any changes to our policy to immediately remove measures as a result of patient safety concerns; however, we proposed to codify that policy at 42 CFR 419.46(h)(2).

We did not receive any public comments and are finalizing our proposal to codify at 42 CFR 419.46(h)(2) our policy to immediately remove measures as a result of patient safety concerns as proposed.

(2) Consideration Factors for Removing Measures

In the CY 2013 OPPS/ASC final rule with comment period, we finalized a set of factors[111] for determining whether to remove measures from the Hospital OQR Program (77 FR 68472 through 68473). These factors are:

- *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).
- *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes.
- *Factor 3.* A measure does not align with current clinical guidelines or practice.
- *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences such as patient harm.

In addition, we refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66769). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

The benefits of removing a measure from the Hospital OQR Program are assessed on a case-by-case basis (79 FR 66941 through 66942). In the proposed rule, we noted that, under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We also noted that in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967), a similar measure removal policy was finalized for the ASCQR Program.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37177 through 37178), we

[109] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

[110] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[111] We note that we previously referred to these factors as ''criteria'' (for example, 77 FR 68472 through 68473); we now use the term ''factors'' in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

proposed to: (1) Update measure removal Factor 7; (2) add a new removal Factor 8; and (3) codify our measure removal policies and factors at 42 CFR 419.46(h) effective upon finalization of the CY 2019 OPPS/ASC final rule and for subsequent years. We also provided clarification of our ''topped-out'' criteria.

(3) Update To Measure Removal Factor 7

As shown above, Factor 7 under the Hospital OQR Program states, ''collection or public reporting of a measure leads to negative unintended consequences *such as* patient harm.'' In contrast, under the ASCQR Program, Factor 7 reads as follows, ''collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm'' (79 FR 66967). We believe the wording in the ASCQR Program is more appropriate because measures causing patient harm would be removed from the program immediately, outside of rulemaking, in accordance with our previously finalized policy to immediately remove measures as a result of patient safety concerns (74 FR 60634 and discussed above). Therefore, in the proposed rule, we proposed to change measure removal Factor 7 in the Hospital OQR Program to ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm'' such that it aligns with measure removal Factor 7 in the ASCQR Program.

Comment: Several commenters supported CMS' proposal to update measure removal Factor 7 to read, ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm'' to align with the ASCQR Program.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal as proposed to revise measure removal Factor 7 to read, ''collection or public reporting of a measure leads to negative unintended consequences other than patient harm.''

(4) New Measure Removal Factor 8

In the CY 2019 OPPS/ASC proposed rule (83 FR 37178 through 37179), we proposed to adopt an additional factor to consider when evaluating measures for removal from the Hospital OQR Program measure set:

- *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the proposed rule and this final rule with comment period with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the Hospital OQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other Federal and State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for health care providers to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the measure, but, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of the proposed rule and this final rule with comment period. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: Patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the Hospital OQR Program, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the Hospital OQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries, and used to inform their choice of facility. In these cases, removing the measure from the Hospital OQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor assessing costs versus benefits on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care facilities to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We refer readers to section XIII.B.4.b. of the proposed rule (83 FR 37179 through 37186), where we proposed to remove two measures based on this proposed measure removal factor. In the proposed rule, we noted that we also proposed this same removal factor for the ASCQR Program in section XIV.B.3.b. of the proposed rule (83 FR 37195 through 37196), as well as for other quality reporting and value-based purchasing programs for FY 2019 including: The Hospital Value-Based Purchasing (VBP) Program (83 FR 20409), the Hospital IQR Program (83 FR 20472); the PPS-exempt Cancer

Hospital Quality Reporting (PCHQR) Program (83 FR 20501 through 20502); the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (83 FR 20512); the Hospice Quality Reporting Program (HQRP) (83 FR 20956); the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (83 FR 21000); the Skilled Nursing Facility Quality Reporting Program (SNF QRP) (83 FR 21082); and the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program (83 FR 21118).

We invited public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

Comment: Several commenters supported CMS' proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. A few commenters noted that this removal factor will help CMS to remove unnecessary cost and burden from the Hospital OQR Program and allow providers of care to focus on improving quality through innovation. Commenters also praised CMS for aligning this and other removal factors across quality reporting programs.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to add a new measure removal Factor 8. A few commenters requested clarification on the types of costs that CMS will consider and requested transparency in the process of evaluation in the costs and benefits of measures. One commenter expressed concern that the costs described under measure removal Factor 8 are not defined. One commenter noted that there are costs associated with changing measures to facilities, providers, and measure developers. Another commenter expressed concern that CMS may deem a measure too costly to implement, while providers and patients may continue to find it meaningful. Commenters also recommended direct and indirect costs that CMS may consider in evaluating measures under measure removal Factor 8. These costs included those associated with: (1) Measures that require data collection from multiple data sources, rather than just one; (2) contracting with vendors; (3) tracking performance and investing in resources for quality improvement. One commenter stated it opposed the new factor unless costs and benefits are defined as only costs and benefits to beneficiaries and the public.

Response: As noted in the proposed rule (83 FR 37176), we have defined costs, for the purpose of evaluating measures under proposed measure removal Factor 8, as including but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). This was not intended to be a complete list of the potential factors to consider in evaluating measures. In addition, as we apply this measure removal factor in future rulemaking, we will describe our rationale for the removal of a measure and will include the costs and benefits we considered.

We thank commenters for their suggestions regarding additional costs to consider. We will use this feedback as well as input from all stakeholders as we apply measure removal Factor 8 in future rulemaking.

We believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining any specific measure in the Hospital OQR Program. However, we also believe that while a measure's use in the Hospital OQR Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing high-quality care and providing publicly reported data regarding the quality of care available. We note that we intend to assess the costs and benefits to program stakeholders, including but not limited to, those listed above. Therefore, we intend to consider the benefits, especially those to patients and their families, when evaluating measures under this measure removal factor. As noted above, we have offered a definition of costs. However, this was not intended to be a complete list of the potential factors to consider in evaluating measures and we intend to consider the additional examples of cost described in public comment, including the costs and benefits to beneficiaries and the public, as recommended by some commenters.

Comment: A few commenters recommended that CMS seek input from hospitals, physicians, and other stakeholders when evaluating the costs and benefits of quality reporting.

Response: We thank the commenters for their feedback and note that we will consider stakeholder input when evaluating both the costs of quality reporting as well as the benefits of collecting and reporting quality data. As stated above, we intend to evaluate costs and benefits for each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining any specific measure in the Hospital OQR Program.

Comment: A few commenters recommended that CMS consider measure sets as a whole as well as the consistency of quality reporting program measure sets. One commenter recommended that when a measure is removed under Factor 8 that it should be replaced by a measure that is easier to implement and aimed at improving care within the same measure domain to avoid gaps in the measure set. A commenter further recommended that measure sets should include actionable process measures that contribute to the outcomes being measured.

Response: We intend to continue to develop a robust measure set for the Hospital OQR Program and appreciate the commenters' feedback. We intend to consider the measure set as a whole, the types of measures in the measure set, and the consistency throughout quality reporting programs when assessing whether the costs outweigh the benefits of a measure's continued use in the Hospital OQR Program. We continually seek ways to improve the Hospital OQR Program measure set, including through identification of more efficient means of capturing data. Retaining a strong measure set that addresses critical quality issues is one benefit that we would consider in evaluating whether a

measure should be potentially removed from the Hospital OQR Program measure set. In addition, we note that in this final rule with comment period, we are not finalizing our proposals to remove two measures under Factor 8: OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients, and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. This is discussed in more detail further below.

After consideration of the public comments we received, we are finalizing our proposal to adopt measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, for the Hospital OQR Program beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, as proposed.

As a result of the finalization of our proposals to update measure removal Factor 7 and add new removal Factor 8 as proposed, the new measure removal factors list for the Hospital OQR Program consists of the following:

- *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures).
- *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes.
- *Factor 3.* A measure does not align with current clinical guidelines or practice.
- *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(5) Codification at 42 CFR 419.46(h)(2) and (3)

In the CY 2019 OPPS/ASC proposed rule (83 FR 37179), we proposed to codify our measure removal policies, including proposals made in the proposed rule, if finalized, at 42 CFR 419.46(h)(2) and (3).

We did not receive any public comments and are finalizing our proposal to codify our measure removal policies, at 42 CFR 419.46(h)(2) and (3) as proposed.

(6) Clarification of Removal Factor 1: ''Topped-Out'' Measures

As noted above, we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66769), where we finalized the criteria for determining when a measure is ''topped-out.'' In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped out'' under the Hospital OQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66942).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37179), we clarified our process for calculating the truncated coefficient of variation (TCOV), particularly for two of the measures (OP–11 and OP–14) proposed for removal from the Hospital OQR Program. In accordance with our finalized methodology (79 FR 66942), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out,'' a measure must have a truncated TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of the measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, OP–11 and OP–14—assess the rate of rare, undesired events for which a lower rate is preferred. For example, OP–11 assesses the use of both a contrast and non-contrast CT Thorax study at the same time, which is not recommended, as no clinical guidelines or peer-reviewed literature supports such CT Thorax ''combined studies.'' However, when determining the TCOV for a measure assessing rare, undesired events, the mean—or average rate of event occurrence—is very low, and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[112] In the proposed rule, we noted that the SD, the variability statistic, is the same in magnitude for measures assessing rare and non-rare events.

In the proposed rule, we proposed to remove two measures that assess the rate of rare, undesired events for which a lower rate is preferred—OP–11 and OP–14—and refer readers to section XIII.B.4.b.(2)(c) of the proposed rule and this final rule with comment period, where these proposals are discussed in detail. Because by design these measures have maintained very low rates of rare, undesired events (indicating the preferred outcomes), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for OP–11, to calculate the TCOV, we divide the SD by the average rate of patients *not* receiving both contrast and non-contrast abdominal CT (1.0 minus the rate of patients receiving both), rather than the rate of those receiving both types of CT. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

b. Removal of Quality Measures From the Hospital OQR Program Measure Set

In the CY 2019 OPPS/ASC proposed rule (83 FR 37179 through 37186), we proposed to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we proposed to remove (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we proposed to remove—(2) OP–5: Median Time to ECG (NQF #0289); (3) OP 31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); (4) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (5) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); (6) OP–9: Mammography Follow-up Rates (no NQF number); (7) OP–11: Thorax Computed Tomography

[112] Rose-Hulman Institute of Technology. Denominator approaching zero. Available at: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

(CT)—Use of Contrast Material (NQF #0513); (8) OP–12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed); (9) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number); and (10) OP–17: Tracking Clinical Results between Visits (NQF endorsement removed). We proposed to remove these measures under the following removal factors: Proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program; measure removal Factor 3, a measure does not align with current clinical guidelines or practice; measure removal Factor 1, measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); and measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

These proposed measure-specific removals are discussed in detail further below. We also received several general comments regarding these proposals as a whole and are discussing those first.

Comment: Many commenters supported CMS' proposals to remove 10 measures from the Hospital OQR Program measure set. Some noted that the proposals will reduce burden, simplify hospital reporting, and reduce duplication. Several commenters suggested that CMS remove all 10 measures beginning with CY 2020, rather than delaying removal of nine measures until CY 2021. Commenters agreed with CMS' rationale for removals and noted that topped-out or not beneficial measures should be removed as soon as possible.

Response: We thank the commenters for their support. Data collection and reporting for the CY 2020 payment determination has already begun for all nine of the measures proposed for removal. Specifically, as finalized in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), data collection began with Q2, (April 1) of 2018. Thus, by the effective date of this final rule with comment period, hospitals will have already reported almost three quarters of data for these measures. In consideration of hospitals' efforts already exerted, we are finalizing removal of these measures starting with the next proximate payment determination.

Comment: One commenter opposed all of CMS' proposals to remove measures from the Hospital OQR Program, citing its belief that consumers should be offered more quality information, rather than less, that can be used in selecting facilities. Another commenter recommended that CMS maintain the existing measure set and, instead of removing measures, work to reduce provider burden through alignment across programs.

Response: We thank the commenters for their feedback and note our agreement that consumers should be provided with as much valuable quality information as possible. As described in the proposed rule, we proposed to remove these measures because the costs associated with a measure outweigh the benefit of its continued use in the program; the measure does not align with current clinical guidelines or practice, measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); or because performance or improvement on a measure does not result in better patient outcomes. We have identified these and other measure removal factors specifically to ensure that the data provided to consumers is meaningful and valuable. We do not believe it is beneficial to maintain program measures indefinitely. However, we agree that burden should be reduced through program alignment and will continue to seek opportunities to do this. In the CY 2019 OPPS/ASC proposed rule, we proposed several policies to align with the ASCQR Program, including updating our measure removal factors and removing OP–27 and ASC–8, OP–29 and ASC–9, OP–30 and ASC–10, and OP–31 and ASC–11, and we are finalizing several of these aligned proposals in this final rule with comment period.

Comment: One commenter recommended that CMS consider the impact of the proposed removal of OP–5, OP–14, OP–27, OP–29, and OP–30 on the *Hospital Compare* overall hospital ratings.

Response: Although these measure removals will reduce the number of outpatient measures in the Hospital Overall Star Ratings, a representative measure set remains and includes OP–32: 7-day visit rate after colonoscopy, OP–4: Aspirin on arrival, OP–22: Patient Left Without Being Seen, OP–23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival, OP–33: External Beam Radiotherapy for Bone Metastases, OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention, and OP–18: Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients. Additional measures, including surgery and chemotherapy measures, may be considered for adoption in future years. (We refer readers to our web page at: *https://www.medicare.gov/hospitalcompare/About/Hospital-overall-ratings.html* for a discussion of *Hospital Compare* overall hospital ratings.)

(1) Measure Removal for the CY 2020 Payment Determination and Subsequent Years—Removal of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

For the CY 2020 payment determination and subsequent years, we proposed to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099), where we adopted OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process-of-care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the HOPD among health care personnel (HCP), who can serve as vectors for influenza transmission.

In the proposed rule, we proposed to remove OP–27, beginning with the CY 2020 payment determination under our proposed measure removal Factor 8 because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart-abstraction of patient data because influenza vaccination among healthcare personnel can be calculated through review of records maintained in

administrative systems and because facilities have fewer healthcare personnel than patients. As such, OP–27 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIII.B.4.a. of the proposed rule and this final rule with comment period, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the Hospital OQR Program measure set, we recognized that some facilities face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the Centers for Disease Control and Prevention (CDC) estimates takes an average of 263 minutes per facility.[113]

Furthermore, submission via NHSN requires the system security administrator of participating facilities to re-consent electronically, ensure that contact information is kept current, ensure that the hospital has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every two months and changing their password, create a monthly reporting plan, and ensure the facility's CCN information is up-to-date. Unlike acute care hospital which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, HOPDs are only required to participate in NHSN to submit data for this one measure.

In our assessment, we also considered that the vast majority (99.7 percent) of Hospital OQR Program eligible hospitals already report this measure in the Hospital IQR Program for workers providing any services to inpatient care. The Hospital IQR Program measure includes the vast majority of all hospital personnel since many workers in outpatient departments provide services to both inpatient and outpatient departments (adopted at 76 FR 51631 through 51633). These workers include most emergency department clinicians, specialists such as pharmacists and imaging professionals, and custodians and other support staff working across the hospital.

We continue to believe that the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure provides the benefit of protecting patients against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among patients, such as numerous healthcare employer requirements for health care personnel to be vaccinated against influenza.[114] [115] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure through the Quality Payment Program (QPP).[116] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. We remain responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[117] Thus, the public health concern of influenza immunization is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discussed in section XIII.B.4.a of the proposed rule, where we proposed to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative, described in section I.A.2. of the proposed rule and this final rule with comment period. In our assessment of the Hospital OQR Program measure set, we prioritized measures that align with this Initiative's framework as the most important to the Hospital OQR Program's population. Our assessment concluded that while the OP–27 measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this chart-abstracted measure.

For these reasons, we proposed to remove OP–27: NHSN Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the Hospital OQR Program beginning with the CY 2020 payment determination and for subsequent years. In the proposed rule, we noted that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We also noted that a similar measure was also proposed for removal from the ASCQR Program in section XIV.B.3.c. of the proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21104).

Comment: Several commenters supported CMS' proposal to remove OP–27 from the Hospital OQR Program measure set, and noted that the proposal will reduce burden and costs to hospitals and that levels of vaccination of health care employees is already very high.

Response: We thank the commenters for their support regarding the burden associated with the OP–27 measure.

Comment: Several commenters opposed CMS' proposal to remove OP–27 from the Hospital OQR Program. A few commenters expressed concern that influenza is a critical public health issue and that influenza vaccination coverage of healthcare workers helps create a safe environment for patients, visitors, and employees. A few commenters expressed concern that removal of OP–27 would result in lower vaccination rates among healthcare workers. A few commenters noted that the Medicare population may be more susceptible to vaccine preventable illnesses such as influenza.

Response: We thank these commenters for their input. We agree that influenza vaccination for both patients and healthcare personnel is important in the outpatient hospital setting, as well as other healthcare

[113] CDC, National Healthcare Safety Network (NHSN). Five-Step Enrollment for Acute Care Hospitals/Facilities. Available at: *https://www.cdc.gov/nhsn/acute-care-hospital/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

[114] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm*.

[115] CDC Influenza Vaccination Coverage Among Health Care Personnel—United States, 2013–14 Influenza Season. Available at: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm*.

[116] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures*.

[117] Ibid.

settings, and we believe that these two activities are both intended to address the public health concern of reducing influenza infection.

However, while we agree that Medicare beneficiaries may have additional risk of contracting influenza, as noted in our proposal, we believe the effects of removing this measure from the Hospital OQR Program are mitigated as the issue is addressed by other initiatives such as State laws and employer programs that require influenza vaccination of healthcare workers. Because of this, we do not believe that retaining this measure would result in lower rates of vaccination coverage among healthcare personnel. Further, we have retained the measure in the Hospital IQR Program (83 FR 41579), thus requiring reporting in the short-term, acute care hospital setting. In addition, we believe that the burden of this measure on hospitals outweighs the limited benefit of addressing this topic again under the Hospital OQR Program in addition to the many other vaccination initiatives.

Comment: A few commenters stated that OP–27 plays a critical role in the CMS Quality Strategy and the National Quality Strategy in terms of immunization efforts. A few commenters suggested that removal of the measure would create greater inconsistency across quality reporting programs.

Response: We agree that influenza is a critical public health issue that is part of the CMS Quality Strategy and the National Quality Strategy. Through our Meaningful Measures Initiative, it is our goal to ensure that we are addressing high-impact measure areas that safeguard public health while minimizing the level of burden for providers and suppliers. We continue to believe in the importance of influenza vaccination coverage for health care workers, particularly in acute care settings, and have retained this measure in the Hospital IQR Program (83 FR 41579) in order to address this concern.

As we noted above, the burden of reporting this measure is greater for outpatient hospitals compared to the relative burden for hospitals participating in the Hospital IQR and HAC Reduction Programs. The entire burden of registering for and maintaining access to the CDC's NHSN system is due to this one measure; whereas hospitals paid under IPPS, participating in the Hospital IQR Program, the HAC Reduction Program and the Hospital VBP Program, for example, must register and maintain NHSN access for several healthcare safety measures, not just one. However, we note that, beyond the Hospital OQR Program, HOPDs may independently choose to voluntarily report data to NHSN on vaccination rates using the NHSN Healthcare Personnel Safety Component.

Comment: One commenter stated that the cost associated with mitigating an influenza outbreak outweighs the cost of retaining OP–27 in the Hospital OQR Program.

Response: As we noted above, we have retained the measure in the Hospital IQR Program (83 FR 41579) in order to address concerns about influenza as a public health issue. In addition, as noted above, we believe the effects of removing this measure from the Hospital OQR Program are mitigated as the topic is addressed by other initiatives such as State laws and employer programs that require influenza vaccination of healthcare workers.[118] [119] As a result, we do not believe removing this measure from the Hospital OQR Program will result in lower rates of vaccination coverage among healthcare personnel in the HOPD setting or increase the risk of an outbreak.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to remove OP–27: NHSN Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the Hospital OQR Program beginning with the CY 2020 payment determination and for subsequent years.

(2) Measure Removals for the CY 2021 Payment Determination and Subsequent Years

In the CY 2019 OPPS/ASC proposed rule (83 FR 37181 through 37186), for the CY 2021 payment determination and subsequent years, we proposed to remove: Four measures under proposed measure removal Factor 8; one measure under measure removal Factor 3; two measures under removal Factor 1; and two measures under measure removal Factor 2.

(a) Measure Removals Under Finalized Removal Factor 8: OP–5, OP–29, OP–30, and OP–31

In the proposed rule, we proposed to remove four measures under measure removal Factor 8, which is being finalized in this final rule with comment period, for the CY 2021 payment determination and subsequent years: OP–5, OP–29, OP–30, and OP–31. In the proposed rule, we noted that if proposed measure removal Factor 8 was not finalized, removal of these measures would also not be finalized.

The proposals are discussed in more detail below. In the proposed rule, we noted that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but we decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

- Removal of OP–5: Median Time to ECG (NQF #0289)

We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865) where we adopted OP–5: Median Time to ECG (NQF #0289) beginning with the CY 2009 payment determination.[120] This chart-abstracted measure assesses the median number of minutes before outpatients with heart attack (or chest pain that suggests a possible heart attack) received an electrocardiograph (ECG) test to help diagnose heart attack.

We proposed to remove the OP–5 measure beginning with the CY 2021 payment determination under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. As noted above, OP–5 is a chart-abstracted measure, which can be potentially more challenging for facilities to report than claims-based or structural measures. Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. As described in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure

[118] CDC. Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[119] CDC Influenza Vaccination Coverage Among Health Care Personnel—United States, 2013–14 Influenza Season. Available at: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm.*

[120] This measure was formerly called ''ED–AMI–4—Median Time to Electrocardiogram (ECG)'' in the cited **Federal Register**.

removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration that, although this measure is not topped-out, we have come to the conclusion that the benefit of this measure is limited. Based on our analysis of data submitted by 1,995 hospitals from Quarter 3 in 2016 through Quarter 2 in 2017 the variation in average measure performance between hospitals is minimal, with a difference in median time to ECG of less than two minutes between the 75th and 90th percentile hospitals. Furthermore, the difference between the 25th and 75th percentile, distinguishing between high and low performers, is only 5.5 minutes. Given clinical guidelines recommend that ECG be obtained within 10 minutes of arrival to the emergency department (ED), we do not believe this difference is clinically significant and further indicates that variations are not sufficiently large to inform beneficiary decision-making to justify the costs of collecting the data.[121] These data are demonstrated in the table below.

Differences in Performance for OP-5: Median Wait Time to ECG

Period	Number of Hospitals	25th Percentile	75th Percentile	90th Percentile
2016 Q3 - 2017 Q2	1,995	11.0 minutes	5.5 minutes	3.8 minutes

We believe that the minimal variation in hospital performance does not help beneficiaries to make informed care decisions, since distinguishing meaningful differences in hospital performance on this measure is difficult. As such, the measure benefit is limited, and no longer meaningfully supports program objectives of informing beneficiary choice.

Thus, we believe that costs and burdens to both facilities and CMS such as program oversight, measure maintenance, and public display, associated with keeping this measure in the program outweigh the limited benefit associated with the measure's continued use. Therefore, we proposed to remove OP–5: Median Time to ECG from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

Comment: Many commenters supported CMS' proposal to remove OP–5. One commenter stated that the burden of collecting data for this chart-abstraction measure exceeds the value. Many other commenters praised CMS' measure removals in general due to the resulting burden reduction.

Response: We thank the commenters for their support.

Comment: A few commenters recommended retaining OP–5. One commenter noted that ECG findings are important in managing acute coronary symptoms and affect patient morbidity. This commenter also noted that it is not overly burdensome to report the measure. Another commenter recommended that the measure be retained and revised so that patients admitted for observation or inpatient care are included.

Response: We thank commenters for this feedback. We agree that ECG findings are important, but our assessment indicates that there is minimal variation in hospital performance on this measure, and therefore, the opportunity to improve the management and patient morbidity associated with acute coronary symptoms is severely limited. In addition, we disagree that the measure is not burdensome to report overall, as it requires chart-abstraction. Many commenters supported removal and cited burden reduction as a benefit of this proposal. As a result, we believe it is appropriate to remove this measure and we do not intend to retain or revise it.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to remove OP–5: Median Time to ECG from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

- Proposal To Remove OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) where we adopted OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' (78 FR 75099). This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of 10 years.

In the proposed rule, we proposed to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75099 through 75100) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we noted concern in the proposed rule that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters, and

[121] Diercks et al. 2006. Door-to-ECG time in patients with chest pain presenting to the ED. AJEM.

interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. We noted in the proposed rule that removing OP–29 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we also acknowledged that we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. In the proposed rule, we noted another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539), which measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcomes measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, in the proposed rule, we noted our belief that the potential benefits of keeping OP–29 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) [122] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we noted that the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. In the proposed rule, we noted that although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[123] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of the proposed rule and this final rule with comment period. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discussed in section XIV.B.3.b. of the proposed rule, where we proposed to adopt measure removal Factor 8, we noted that beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the Hospital OQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we noted in the proposed rule that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we proposed to remove OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. In the proposed rule, we noted that we also proposed to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of the proposed rule.

Comment: Several commenters opposed CMS' proposal to remove OP–29 from the Hospital OQR Program. A few commenters expressed concern that physicians may not follow the recommended guidelines for colonoscopy screenings and noted that there is a potential for patient harm from unnecessary colonoscopy screenings that pose significant costs. One commenter believed that solely retaining the measure in MIPS is insufficient because the measure is voluntary in that program. A few commenters stated that OP–29 and OP–32 assess distinct and different aspects of colonoscopies, because OP–32 focuses on coordination and does not evaluate the interval between colonoscopies or the appropriate use of care. One commenter noted that OP–29 and OP–32 fall into different Meaningful Measures categories, Preventable Healthcare Harm and Admissions and Readmissions, respectively. Some commenters recommended retaining OP–29 to achieve a holistic approach to measuring the quality of care in this clinical area. One commenter asserted that OP–29 is not overly burdensome to collect and report. Some commenters disagreed with CMS' assessment that the costs of the measure outweigh the benefits.

Response: Although MIPS-eligible clinicians may voluntarily select measures from a list of options, in crafting our proposal, we believed that MIPS reporting would mitigate the impact of removing this measure and provide some meaningful data in this clinical area. After considering the commenters' views, however, we acknowledge that although a similar measure is available in the QPP, OP–29 provides valuable information to beneficiaries specifically about the outpatient hospital setting, where high volumes of colonoscopies are performed. We agree that adherence to clinical guidelines for colonoscopy screening intervals is an important issue due to many studies that document inappropriate use.[124] [125] [126] One study

[122] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Available at: *https://qpp.cms.gov/mips/quality-measures*.

[123] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

[124] Sheffield et al. 2013. Potentially Inappropriate Screening Colonoscopy in Medicare Patients:

showed high rates of inappropriate colonoscopies performed in older adult populations: 10 percent in adults aged 70–75, 39 percent in adults aged 76–85, and 25 percent in adults aged ≥86.[127] Thus, we believe that OP–29 is a critical measure for the Hospital OQR Program because there is demonstrated substantial overuse of surveillance colonoscopies among low-risk patients,[128] with research showing that colonoscopies are often recommended at shorter intervals than are advised by guidelines among patients with normal colonoscopy results.[129] We believe it is especially important to assess this topic due to the high-volume of these procedures that occur in the outpatient setting.

Furthermore, while OP–29 and OP–32 assess the topic of colonoscopies generally, we acknowledge that they assess distinct clinical areas. OP–32 tracks adverse patient outcomes that result in unplanned hospital visits, whereas, OP–29 provides information about colonoscopies occurring at inappropriate intervals that may increase costs to beneficiaries and to CMS, a priority of our Meaningful Measures Initiative. While OP–32 provides vital data about patient outcomes after colonoscopies, OP–29 focuses on adherence to guideline recommendations for screening colonoscopy follow-up intervals, as noted by NQF's evaluation report.[130]

Despite the costs and burdens of chart-abstraction or the presence of other measures assessing a similar clinical topic, after considering incoming comments and reevaluating our data, we now believe OP–29 is a more critical measure for the Hospital OQR Program than initially perceived in the proposed rule. Specifically, as discussed above, upon reviewing the measure set as a whole, we now believe that OP–29 assesses a distinct clinical area not addressed by OP–32. Further, although we noted that OP–29 requires the burden of chart-abstraction to report, we believe this measure is significantly less burdensome than OP–30 due to the significant burden of obtaining patient histories required for that measure. We also appreciate commenters' feedback that OP–29 is not overly burdensome to report. Because this measure tracks the number of patients who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report, we believe it provides important information to beneficiaries on the avoidance of inappropriate endoscopies/colonoscopies. OP–29 evaluates overutilization that can lead to the overuse of resources and unnecessary risks to beneficiaries from possible procedural complications and harms.

Accordingly, after considering the public comments we received and upon further review of the benefits of the measure, we no longer believe that the costs associated with this measure outweigh the benefit of its continued use in the Hospital OQR Program.

In section I.A.2. of the proposed and this final rule with comment period, we describe our Meaningful Measures Initiative that is intended to reduce costs and minimize burden. We believe that while removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity, retaining it provides pertinent information about colonoscopies occurring at inappropriate intervals that may contribute to increased costs to beneficiaries and to CMS, a priority of our Meaningful Measures Initiative. Therefore, we are not finalizing our proposal to remove this measure. We believe retaining this measure is responsive to those comments as it is a valuable process measure and assesses a distinct clinical area.

Comment: A few commenters stated that OP–29 should be retained to promote program alignment across outpatient settings and allow for comparisons between facility types.

Response: We have considered program alignment by adding and removing measures in tandem for the ASCQR and Hospital OQR Programs, such as ASC–9/OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. As noted above, we adopted OP–29 into the Hospital OQR Program because we believe it is important for HOPDs to be active partners in avoiding inappropriate use and ensuring that beneficiaries at their facilities are referred for follow-up care at appropriate intervals in alignment with current guidelines. As stated above, we are not finalizing our proposal to remove OP–29. We are similarly retaining the corresponding measure (ASC–9) in the ASCQR Program in section XIV.B.3.c. of this final rule with comment period.

Comment: One commenter did not support CMS' proposal to remove OP–29 because it is included in the Core Quality Measures Collaborative (CQMC) Gastroenterology Core Set and is widely used in the private sector.

Response: The CMS CQMC identifies core sets of quality measures that payers have committed to using for reporting as soon as feasible.[131] The guiding principles used by the Collaborative in developing the core measure sets are that they be meaningful to patients, consumers, and physicians, while reducing variability in measure selection, collection burden, and cost. Its goal is to establish broadly agreed upon core measure sets that could be harmonized across both commercial and government payers.[132] We agree that the inclusion of OP–29 in the CQMC Gastroenterology Core Set speaks to its clinical value. However, although we are retaining OP–29 for the reasons described in this section, we note that the inclusion of measures in the CQMC Core Sets does not necessitate retention in the Hospital OQR Program.

Comment: One commenter recommended that CMS retain the measure and explore how to automate tracking of the information to reduce the resource-intensive use of chart-abstracted data.

Response: We thank the commenter for the suggestion regarding automated data submission and will take this into consideration for the future. As discussed in section I.A.2 of this final rule with comment period, our Meaningful Measures Initiative prioritizes the least burdensome measure sets for our quality reporting programs, and we will continue to evaluate the Hospital OQR Program measure set through this framework. We continually seek opportunities to reduce

Variation by Provider and Geographic Region. JAMA Intern Med.

[125] Schoen R. E., Pinsky P. F., Weissfeld J. L., et al. Utilization of surveillance colonoscopy in community practice. Gastroenterology. 2010;138(1):73–81. doi: 10.1053/j.gastro.2009.09.062.

[126] Krist, AH, Jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.

[127] Sheffield et al. 2013. Potentially Inappropriate Screening Colonoscopy in Medicare Patients: Variation by Provider and Geographic Region. JAMA Intern Med.

[128] Schoen R. E., Pinsky P. F., Weissfeld J. L., et al. Utilization of surveillance colonoscopy in community practice. Gastroenterology. 2010;138(1):73–81. doi: 10.1053/j.gastro.2009.09.062.

[129] Krist, AH, Jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.

[130] NQF #0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients, Date Submitted: Jul 09, 2012 National Quality Form, Stage 1 Concept Submission and Evaluation Worksheet 1.0.

[131] Core Measures. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.*

[132] Ibid.

the reporting burden of our programs but note that collecting data for OP–29 still currently requires chart-abstraction.

Comment: Many commenters supported CMS' proposal to remove OP–29, noting that the proposal reduces burden and duplication between programs. A few commenters noted that the measure was developed to assess provider, rather than facility-level, performance.

Response: We thank the commenters for their support. As noted in our proposal above, this same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about avoiding inappropriate use. While this measure was initially developed at the physician level, it has been field-tested in the HOPD facility setting by the measure stewards (78 FR 75099). Further, we believe it is important for HOPDs to be active partners in avoiding inappropriate use and ensuring that patients at their facilities are referred for follow-up care at appropriate intervals in alignment with current guidelines. In addition, after considering the public comments we received and upon further review of the benefits of the measure, we no longer believe that the costs associated with this measure outweigh the benefit of its continued use in the program as this measure assesses a unique and clinically important topic area not covered otherwise addressed by the Hospital OQR Program measure set.

After consideration of the public comments we received, we are not finalizing our proposal to remove OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years. This measure will remain in the program under our measure retention policies, unless we take future action under our measure removal policies. We note that we also are not finalizing our proposal to remove ASC–9 under the ASCQR Program, and we refer readers to section XIV.B.3.c. of this final rule with comment period for more information.

- Removal of OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75102) where we adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of three or more years since their last colonoscopy documented in the colonoscopy report.

In the proposed rule, we proposed to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102) noting that colonoscopy screening for high risk patients is recommended based on risk factors and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by hospital outpatient departments because colonoscopy screening is commonly performed in these settings (78 FR 75102). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing OP–30 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the Hospital OQR Program, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within 7 days of an outpatient colonoscopy procedure (79 FR 66949). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted OP–32, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66949). Furthermore, the potential benefits of keeping OP–30 in the program are mitigated by the existence of the same measure for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, HOPD providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[133] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients

[133] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of the proposed rule and this final rule with comment period. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the Hospital OQR Program would reduce program complexity. In addition, as we discussed in section XIII.B.4.a. of the proposed rule, where we proposed to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in OQR that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we proposed to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. In the proposed rule, we noted that we also proposed to remove a similar measure in the ASCQR Program in section XIV.B.3.c. of the proposed rule.

Comment: Many commenters supported CMS' proposal to remove OP–30. A few commenters noted that the measure is burdensome and costly to report, in part due to the volume of cases that must be reviewed to identify patients that meet the inclusion and exclusion criteria. Some commenters agreed that the cost of the measure outweighs the benefits due to data collection challenges that are specific to OP–30, due to the extensive patient histories required and because data may need to be obtained from different settings.

Response: We thank the commenters for their support. In addition to the burden of chart-abstraction, we agree with the commenter that pointed out the unique burden of OP–30, which requires that facilities conduct extensive patient histories and contact other facilities in order to obtain documentation of a history of adenomatous polyps.[134] Thus, the costs and burdens are higher for this measure than for the other colonoscopy measure considered for removal, OP–29, which requires less information from patients and does not require historical documentation. We thank the commenter for its feedback on the burden associated with identifying patients meeting the inclusion and exclusion criteria for this measure. We are finalizing our proposal to remove OP–30.

Comment: One commenter noted that the measure specifications for OP–30 will be updated soon and recommended that CMS retain the measure until new guidelines are available. A few commenters disagreed with CMS' assessment that the cost of the measure outweighs the benefit, and one commenter recommended that CMS try to automate tracking of data needed for the measure to reduce its burden.

Response: We understand that the measure steward is planning to update OP–30; however, because these updates will not eliminate the need to collect patient histories, we do not believe such updates will lessen burden. Due to the burden of data collection for this measure, which includes taking extensive patient histories, we believe the costs outweigh the benefits and, therefore, we do not believe it is appropriate to retain the measure. We thank the commenter for the suggestion regarding automated data submission and will take this into consideration for the future. As discussed in section I.A.2 of this final rule with comment period, our Meaningful Measures Initiative prioritizes burden reduction in our quality reporting programs, and we will continue to evaluate the Hospital OQR Program measure set through this framework. We continually seek opportunities to reduce the reporting burden of our programs, but note that currently, collecting data for OP–30 still requires chart-abstraction.

Comment: Several commenters noted that OP–30 was developed and tested as a provider-level measure and they did not believe it is appropriate for the hospital setting. One commenter stated that this measure is already being reported through the MIPS (formerly PQRS) and that MIPS is the appropriate program because OP–30 is a provider-level measure. Another commenter stated that duplicate reporting in CMS' quality reporting programs has caused unnecessary provider burden without adding new information to the pool of quality data available to the public. Another commenter noted that relying on MIPS reporting of this measure is inadequate, as MIPS is a voluntary measure in that program.

Response: We adopted OP–30 into the Hospital OQR Program because we believe it is important for HOPDs to be active partners in avoiding inappropriate use and ensuring that beneficiaries at their facilities are referred for follow-up care at appropriate intervals in alignment with current guidelines. And, while this measure was initially developed at the physician level, it has been field-tested in the HOPD facility setting by the measure stewards (78 FR 75099). As noted in our proposal, this same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about avoiding inappropriate use.

A primary goal of our Meaningful Measures Initiative is to reduce provider burden through the deduplication of measures across quality reporting programs. As discussed above, after considering comments and revaluating our measure sets as a whole, we are not finalizing our proposal to remove OP–29 in order to retain a measure assessing inappropriate use of endoscopies/colonoscopies in the Hospital OQR Program. We believe there may be a measurement gap if both OP–29 and OP–30 are removed and because of the unique burden associated with OP–30, we are finalizing its removal while retaining OP–29. Removing OP–30 while retaining OP–29 best enables us to assess this important clinical area while ensuring that the costs of measure do not outweigh the benefits. Thus, due in part to the duplication of this measure through MIPS in the QPP and the additional burden to hospitals of obtaining patient records, we are finalizing our proposal to remove OP–30 from the Hospital OQR Program measure set beginning with the CY 2021 payment determination, as proposed.

Comment: A few commenters opposed CMS' proposal to remove OP–30 from the Hospital OQR Program. One commenter noted that OP–30 is a cost measure and helps avoid inappropriate use or missed opportunities to screen patients that could result in significant harm to beneficiaries. One commenter

[134] OP–30 Measure Information Form. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776612884.*

expressed concern that physicians may not follow the recommended guidelines for colonoscopy screenings and noted that there is a potential for patient harm from unnecessary colonoscopy screenings that poses significant costs.

Response: We agree that adherence to clinical guidelines for colonoscopy screening intervals is an important issue. Measuring the inappropriate use of colonoscopy screenings is critical to preventing the waste of resources and potential patient harm. In part for this reason, we are retaining OP–29 in the Hospital OQR Program measure set and will continue to require reporting on appropriate follow-up intervals for normal risk patients. We believe that retaining OP–29 in the Hospital OQR Program enables us to address concerns regarding patient harm from unnecessary colonoscopy screenings. Further, due to the unique documentation burden specifically for OP–30, we believe it adds undue burden especially in comparison to OP–29. After considering stakeholder comments, reevaluating our measure sets as a whole, and balancing the clinical value of measures with the costs, we believe it is appropriate to retain OP–29 while finalizing our proposal to remove OP–30.

Comment: One commenter did not support CMS' proposal to remove OP–30 because it is included in the CQMC Gastroenterology Core Set and is widely used in the private sector.

Response: The CMS CQMC Gastroenterology Core Set is a set of measures identified as being meaningful to patients, consumers, and physicians, while reducing variability in measure selection, collection burden, and cost and is intended for use by payers who are part of the CQMC.[135] Because of this, we believe beneficiaries will continue to receive this data to help them make health care decisions. We agree that this measure is valuable to many stakeholders and support its continued reporting through other quality reporting programs and in the private sector. However, due to the measure's requirement to obtain historical patient records, we believe that this measure adds undue burden to HOPDs. In addition, we note that the inclusion of measures in the CQMC Core Sets does not necessitate retention in the Hospital OQR Program.

Comment: A few commenters stated that OP–30 and OP–32 assess distinct different aspects of colonoscopies, because OP–32 focuses on care coordination and does not evaluate the interval between colonoscopies or the appropriate use of care. One commenter noted that OP–30 and OP–32 fall into different Meaningful Measures categories, Preventable Healthcare Harm and Admissions and Readmissions, respectively.

Response: We thank the commenters for their feedback. We agree that OP–30 and OP–32 assess distinct clinical areas but do assess the topic of colonoscopies generally. While OP–32 tracks adverse patient outcomes that result in unplanned hospital visits, OP–30 provides information about colonoscopies occurring at inappropriate intervals for beneficiaries that may contribute to increased costs to beneficiaries and to CMS, a priority of our Meaningful Measures Initiative. However, we believe OP–30 should be removed because it is uniquely burdensome, as described in a previous response. After considering stakeholder comments, reevaluating our measure sets as a whole, and balancing the clinical value of measures with the costs, we believe it is appropriate to remove OP–30. We note that our retention of OP–29 allows us to continue to address inappropriate use of colonoscopy screening.

After consideration of the public comments we received, we are finalizing our proposal to remove OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years. We refer readers to section XIV.B.3.c. of this final rule with comment period where we are removing a similar measure from the ASCQR Program.

- Proposal To Remove OP–31: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75103) where we adopted OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination and subsequent years. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a pre-operative and post-operative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for facilities to collect and report the measure (79 FR 66947). Specifically, we were concerned that the results of the survey used to assess the pre-operative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for facilities to have knowledge of the visual function of the patient before and after surgery (79 FR 66947). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66947). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for OP–31 for 3 months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772854917*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of OP–31 for an additional nine months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773786593*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66948), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In the proposed rule, we proposed to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 and for subsequent years under our proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted OP–31 because we believe facilities should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66947). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for facilities to report this measure due

[135] Core Measures. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html*.

to the difficulty of tracking care that occurs outside of the HOPD setting.

In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the facility would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and facilities, so a facility would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of OP–31 to CMS, especially for small facilities with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 59 [136] facilities have reported this measure to CMS, compared to approximately 4,798 total facilities for all other measures, resulting in only 1.2 percent of facilities reporting. Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses facility performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period in which commenters expressed concern that the incomplete display of data associated with voluntary reporting is confusing and not meaningful to beneficiaries and other consumers (79 FR 66947). Furthermore, commenters feared that the display of data from some hospitals, but not others, would lead some patients to conclude that some hospitals are more committed to improving cataract surgery. As described in section I.A.2. of the proposed rule and this final rule with comment period, we strive to ensure that beneficiaries are empowered to make decisions about their health care using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Thus, we stated that we believed the high technical and administrative costs of this measure, coupled with the high technical and administrative burden, outweigh the limited benefit associated with the measure's continued use in the Hospital OQR Program. As discussed in section I.A.2. of the proposed rule and this final rule with comment period, above, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believed that removing this measure from the Hospital OQR Program will reduce program burden, costs, and complexity. Therefore, we proposed to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. In the proposed rule, we noted that we also proposed to remove a similar measure under the ASCQR Program in section XIV.B.3.c. of the proposed rule.

Comment: A few commenters opposed all of CMS' proposals to remove measures, including OP–31.

Response: In response to these comments requesting that measures, including OP–31, be retained, we reevaluated our measures and data. We found that a core group of facilities (between 52 and 66 for the CY 2017 through CY 2019 payment determinations) reported on this voluntary measure. Although only a subset of hospitals voluntarily report data for this measure, we believe this measure is considered very meaningful by those that do report; a subset of reporting hospitals report consistently (11 hospitals submitted consistently for the CY 2017 through CY 2019 payment determinations). Because this subset of hospitals has consistently reported this measure we are able to make the data publicly available year after year—in this case, for the CYs 2017, 2018, and 2019 payment determinations.[137] We believe providing data on this voluntary measure is still helpful for the public because it shows how a HOPD performs over time and in comparison to other HOPDs even if compared to a small group of HOPDs.

Furthermore, this is the only measure in the Hospital OQR Program measure set that deals with cataract surgery, which is commonly performed in the HOPD setting. If it is removed, the program will have a gap in coverage for this clinical area. As a result, we now believe that this measure maintains coverage in an important clinical area in the Hospital OQR Program and meaningful information can be provided to consumers regarding those facilities. In addition, when this measure was made voluntary in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948), commenters expressed support, indicating that some stakeholders value the measure.

Furthermore, we have reassessed our evaluation that the costs of this measure outweigh the benefits. Due to the voluntary nature of the measure, we believe that it is inherently not more burdensome than valuable. Because hospitals are not required to submit data, those that do not have the capacity to report, do not have to, thus creating no extra burden. Those that do report, do so voluntarily and have continued to report over the years—specifically since the CY 2015 reporting period—despite any burdens. Because of this, we believe the measure is meaningful to the core group of facilities that do consistently report.

After consideration of public comments and reassessing our analysis, we are not finalizing our proposal to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years. This measure will remain in the program under our measure retention policies, unless we take future action under our measure removal policies.

Comment: Many commenters supported CMS' proposal to remove OP–31. A few commenters noted that data collection for this measure is difficult as it requires following up with clinical settings outside of the hospital. Another commenter supported removal and noted that the measure is meant for physician level-use, rather than facility-level reporting. One commenter questioned the validity of the measure and noted that it allows providers to use different surveys to collect measure information.

Response: We thank the commenters for their support. As noted in the proposed rule, we agree that data collection for this measure may be difficult, and as a result in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66948), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years. While this measure was initially developed at the physician level, it has been field-tested in the HOPD facility setting by the measure stewards (78 FR 75099).

[136] OQR Hospital Compare. Available at: *https://data.medicare.gov/Hospital-Compare/Timely-and-Effective-Care-Hospital/yv7e-xc69.*

[137] *Hospital Compare: https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html.*

In addition, we believe it is important for HOPDs to be active partners in care with physicians and other clinicians using their facility and this measure is an opportunity for hospitals to demonstrate this capability if they choose to report data. Further, as noted above, we no longer believe that the costs of this measure outweigh the benefits, as the measure is meaningful to the core group of outpatient hospitals that do consistently report and can provide valuable data to consumers on those specific facilities. While data collection for this measure can be difficult, those facilities that choose to report do so because they have systems in place to data from ophthalmologists' medical records. We agree that as a voluntary measure, only a subset of hospitals report on the measure, but note it is a meaningful measure to beneficiaries given that our analyses show that a consistent group of facilities report data on this measure. So, while data is not available for all facilities, the data that is available is meaningful. In addition, this measure has been appropriately validated for the population for which it being used, even acknowledging that various survey methods can be used.[138]

This same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about this important outcome for beneficiaries.

After consideration of the public comments we received and reassessing our analysis, we are not finalizing our proposal to remove OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. We are also retaining a similar measure in the ASCQR Program (ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery) in section XIV.B.3.b. of this final rule with comment period.

(b) Measure Removal Under Removal Factor 3: OP–9: Mammography Follow-Up Rates

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–9: Mammography Follow-up Rates beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of patients with mammography screening studies that are followed by a diagnostic mammography, ultrasound, or MRI of the breast in an outpatient or office setting within 45 days. In the proposed rule (83 FR 37184 through 37185), we proposed to remove this measure under measure removal Factor 3, a measure does not align with current clinical guidelines or practice.

An examination of the measure specifications [139] shows that recent changes in clinical practice are not incorporated into the measure calculation. Since development of this measure in 2008, advancements in imaging technology and clinical practice for mammography warrant updating the measure's specifications to align with current clinical practice guidelines and peer-reviewed literature. Specifically, findings from the annual Literature Reviews and Environmental Scans conducted by the measure developer suggest that there is additional clinical benefit in performing adjuvant digital breast tomosynthesis (DBT) concomitant with full-field digital mammography (FFDM) or conventional mammography (currently included in the measure denominator), especially in women with dense breast tissue.[140] [141] [142] In addition, in 2016, the American College of Radiology (ACR) updated its Breast Cancer Screening Appropriateness Criteria® to include DBT.[143] The ACR notes that DBT can better detect potential false-positive findings without the need for recall. Furthermore, the cancer detection rate is increased with use of DBT compared with traditional mammography alone.[144] A 2014 study published in the Journal of the American College of Radiology assessed the utilization of DBT among physician members of the Society of Breast Imaging and found that 30 percent of respondents reported using DBT concurrent with traditional mammography.[145] With the update of the ACR clinical practice guidelines (that is, the Breast Cancer Screening Appropriateness Criteria®) to include DBT, use of this technology is expected to increase.

As currently specified, the measure does not adequately capture this shift in clinical practice. Thus, we believe this measure as specified does not align with current clinical guidelines or practice, and we proposed to remove OP–9: Mammography Follow-up Rates from the program for the CY 2021 payment determination and subsequent years. We intend to investigate respecification of this measure and consider it for adoption to the program through future rulemaking. Specifically, we will consider ways to capture a broader, more comprehensive spectrum of mammography services including adding diagnostic digital breast tomosynthesis. In the proposed rule, we noted that, in crafting our proposal, we considered removing this measure beginning with the CY 2020 payment determination, but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

Comment: Many commenters supported CMS' proposal to remove OP–9 from the Hospital OQR Program measure set and noted that the measure does not align with clinical guidelines. One commenter noted that the measure is meant for physician-level use, rather than facility-level reporting.

Response: We thank the commenters for their support. We note that while the measure was developed for physician-level use, as we stated when adopting the measure, it has been tested and was determined to be appropriate for the Hospital OQR Program by the consensus-based development process that meets the statutory requirement for adoption of a measure (73 FR 68765).

[138] NQF Measure Evaluation available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=68317*.

[139] Hospital Outpatient Quality Reporting Specifications Manual. Version 11.0a. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776146046*.

[140] Bernardi, D., Macaskill, P., Pellegrini, M., Valentini, M., Fanto, C., Ostillio, L., Houssami, N. (2016). Breast cancer screening with tomosynthesis (3D mammography) with acquired or synthetic 2D mammography compared with 2D mammography alone (STORM–2): a population-based prospective study. Lancet Oncol, 17(8), 1105–1113. doi: 10.1016/s1470–2045(16)30101–2.

[141] Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital Breast Tomosynthesis: A New Diagnostic Method for Mass-Like Lesions in Dense Breasts. Breast J, 22(5), 535–540. doi: 10.1111/tbj.12622.

[142] Pozz, A., Corte, A. D., Lakis, M. A., & Jeong, H. (2016). Digital Breast Tomosynthesis in Addition to Conventional 2DMammography Reduces Recall Rates and is Cost Effective. Asian Pac J Cancer Prev, 17(7), 3521–3526.

[143] Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p.

[144] Ibid.

[145] Hardesty LA, Kreidler SM, Glueck DH. Digital breast tomosynthesis utilization in the United States: a survey of physician members of the Society of Breast Imaging. Journal of the American College of Radiology. 2014. 11(6): 594–599.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to remove OP–9: Mammography Follow-up Rates from the program for the CY 2021 payment determination and subsequent years.

(c) Measure Removals Under Removal Factor 1: OP–11 and OP–14

In the proposed rule (83 FR 37185 through 37186), for the CY 2021 payment determination and subsequent years, we proposed to remove OP–11 and OP–14 under removal Factor 1, measure performance among providers is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The Hospital OQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). We refer readers to section XIII.B.4.a.(6) of the proposed rule, where we clarified and discussed how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred such as OP–11 and OP–14.

For each of these measures, we believe that removal from the Hospital OQR Program measure set is appropriate as there is little room for improvement. In addition, as discussed in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. As such, we believe the burden associated with reporting these measures outweighs the benefits of keeping them in the Hospital OQR Program.

Each measure is discussed in more detail below. In the proposed rule, we also noted that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination but decided on proposing to delay removal until the CY 2021 payment determination and subsequent years to be sensitive to providers' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination.

• Removal of OP–11: Thorax CT Use of Contrast Material

We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766) where we adopted OP–11: Thorax CT Use of Contrast Material (NQF #0513) beginning with the CY 2010 payment determination. This claims-based measure assesses the percentage of thorax studies that are performed with and without contrast out of all thorax studies performed.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP-11: Thorax CT Use of Contrast Material Topped-Out Analysis

Encounters	Number of Hospitals	75th Percentile	90th Percentile	Truncated COV
CY 2012	867	96.9	98.4	0.081
CY 2013	869	97.1	98.5	0.074
CY 2014	796	97.2	98.4	0.065
CY 2015	711	97.4	98.5	0.054

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

• Removal of OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT

We refer readers to the CY 2010 OPPS/ASC final rule with comment period (75 FR 72082) where we adopted OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT beginning with the CY 2012 payment determination and for subsequent years. This claims-based measure assesses the extent to which patients with a headache who have a brain CT also have a sinus CT performed on the same date at the same facility.

Based on our analysis of Hospital OQR Program measure data, we have determined that this measure meets our measure removal Factor 1. These analyses are captured in the table below.

OP-14: Simultaneous Use of Brain Computed Tomography (CT) And Sinus CT Topped-Out Analysis

Encounters	Number of Hospitals	75th Percentile	90th Percentile	Truncated COV
CY 2012	1,478	97.8	98.3	0.012
CY 2013	1,939	97.7	98.2	0.010
CY 2014	2,023	97.6	98.2	0.011
CY 2015	1,101	98.5	98.8	0.007

As displayed in the table above, there is a statistically indistinguishable difference in hospital performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2012.

Therefore, we invited public comment on our proposals to remove: (1) OP–11: Thorax CT Use of Contrast Material, and (2) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT measure for the CY 2021 payment determination and subsequent years as discussed above.

Comment: Many commenters supported CMS' proposals to remove OP–11 and OP–14, noting agreement that the proposals will reduce burden and that the measures have limited use for quality improvement.

Response: We thank the commenters for their support. We agree that these topped-out measures have limited value.

Comment: A few commenters opposed CMS' proposals to remove OP–11 and OP–14. One commenter expressed concern that measures should not be removed from the program based solely on topped-out status. This commenter recommended that CMS ensure the measure is topped-out for a number of years, evaluate whether there are unintended consequences of removal, and continue monitoring performance on topped-out safety measures. Another commenter expressed concern that variation in measure performance exists between high and low performing States.

Response: We thank the commenters for their feedback and note that we would consider re-proposing these measures for the Hospital OQR Program in the future if data and research indicate that performance in this area has declined, thus mitigating any potential unintended consequences of measure removal. In the meantime, however, we believe it is appropriate to remove these topped-out measures from the Hospital OQR Program, as we believe these measures have limited ability to encourage quality improvement or provide beneficiaries with information on differences in quality across hospitals.

We have previously finalized our policy to consider measures for removal if they meet topped-out status (79 FR 66769) and accordingly, we disagree with commenters that topped-out status is not sufficient grounds for measure removal. In addition, ''topped-out'' status is only one of many factors we consider in removing measures. We consider the removal of each topped-out measure on a case-by-case basis, as appropriate, and determine whether a clinical or other quality improvement need for the measure justifies the retention of a topped-out measure that otherwise meets our criteria. We also note that the measures have been topped-out for four years. However, if it becomes evident that performance on this measure topic declines over time, we will consider re-introducing this or similar measures and will do so through the rulemaking process. While slight variation may exist in measure performance, our analyses demonstrate that this variation is statistically indistinguishable.

The Hospital OQR Program has finalized the ''topped-out'' methodology to evaluate variation in performance among HOPDs (79 FR 66769), in line with other quality reporting and value-based purchasing programs including the ASCQR (79 FR 66968), Hospital IQR (80 FR 49641 through 49643), Hospital VBP (79 FR 50055), IPFQR (82 FR 38463 through 38465), and PCHQR (81 FR 57182 through 57183) Programs. Our topped-out methodology does not evaluate variation at the State level, but rather at the level of individual ASCs. Our analyses demonstrate that the variation in performance among HOPDs for these measures is statistically indistinguishable. As shown in the tables above, hospitals performing at the 90th vs. 75th percentile have a rate of 98.5 percent as compared to a rate of 97.4 percent for OP–11 and a rate of 98.8 percent vs. 98.5 percent for OP–14.

After consideration of the public comments we received, we are finalizing our proposals, as proposed, to remove: (1) OP–11: Thorax CT Use of Contrast Material, and (2) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT measure for the CY 2021 payment determination and subsequent years.

(d) Measure Removals Under Measure Removal Factor 2: OP–12 and OP–17

In the proposed rule (83 FR 37186), for the CY 2021 payment determination and subsequent years, we proposed to remove two measures under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes: OP–12 and OP–17. The proposals are discussed in more detail below. As discussed in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believe that removing these measures from the Hospital OQR Program will reduce program burden, costs, and complexity. In addition, we noted that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination but decided on proposing to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for this measure begins during CY 2018 for the CY 2020 payment determination.

- Removal of OP–12: The Ability for Providers With HIT To Receive Laboratory Data Electronically Directly Into Their Qualified/Certified EHR System as Discrete Searchable Data

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72076) where we adopted OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data

beginning with the CY 2012 payment determination. This web-based measure assesses the extent to which a provider uses an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system that incorporates an electronic data interchange with one or more laboratories allowing for direct electronic transmission of laboratory data in the EHR as discrete searchable data elements. In the proposed rule, we proposed to remove OP–12 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–12 is a process measure that tracks the transmittal of data but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of the proposed rule and this final rule with comment period, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of the proposed rule and this final rule with comment period, one of the goals of our Meaningful Measures Initiative is to utilize measures that are ''outcome-based where possible.'' We do not believe OP–12 adds to these goals. In fact, we believe that provider performance in the measure is not an indicator for patient outcomes and continued collection provides little benefit.

Therefore, we proposed to remove OP–12 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

Comment: Many commenters supported CMS' proposal to remove OP–12. One commenter noted that the measure does not directly assess quality of care or patient outcomes.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to remove OP–12. One commenter requested that CMS revise the measure so that it assesses quality of care in addition to HIT functionality. Another commenter recognized the value of removing OP–12 from the program but recommended that CMS continue to promote interoperability in the outpatient hospital setting.

Response: We thank the commenters for their feedback. We note that as a structural measure, OP–12 is limited to evaluating whether or not a provider uses an ONC-certified EHR system, and does not provide data on patient outcomes. We agree that a measure assessing the impact of EHR use on quality would be valuable and we intend to identify and consider other measures that assess interoperability and care quality for future inclusion in the program as appropriate measures become available. Due to this measure's limitations as a structural measure, we do not believe it is possible to revise the measure in order to assess patient outcomes or quality of care directly. Due to the limitations of OP–12, we believe it is appropriate to remove this measure from the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to remove OP–12 beginning with the CY 2021 payment determination and for subsequent years.

- Removal of OP–17: Tracking Clinical Results Between Visits

We refer readers to CY 2011 OPPS/ASC final rule with comment period (75 FR 72085) where we adopted OP–17: Tracking Clinical Results between Visits beginning with the CY 2013 payment determination. This web-based measure assesses the extent to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies (including common preventive screenings), or patient referrals. In the proposed rule, we proposed to remove OP–17 beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 2, performance or improvement on a measure does not result in better patient outcomes.

OP–17 is a process measure that tabulates only the ability for transmittal of data but does not directly assess quality or patient outcomes. In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72075), commenters expressed concern that the measure only assesses HIT functionality and does not assess the quality of care provided. As discussed in section I.A.2. of the proposed rule and this final rule with comment period, one of the goals of our Meaningful Measures Initiative is to reduce burden associated with payment policy, quality measures, documentation requirements, conditions of participation, and health information technology. As also discussed in section I.A.2. of the proposed rule and this final rule with comment period, one of the goals of our Meaningful Measures Initiative is to utilize measures that ''outcome-based where possible.'' We do not believe OP–17 supports this goal. In fact, we believe that provider performance in the measure does not improve patient outcomes and continued collection provides little benefit. Therefore, we proposed to remove OP–17 from the Hospital OQR Program beginning with the CY 2021 payment determination and for subsequent years.

Comment: Many commenters supported CMS' proposal to remove OP–17. A few commenters noted that the measure does not directly assess quality of care or patient outcomes.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to remove OP–17. One commenter noted that the ability to transfer electronic records can hasten diagnosis and treatment and reduce service duplication. Another commenter recognized the value of removing OP–17 from the ASCQR Program, but recommended that CMS continue to promote interoperability in the outpatient hospital setting.

Response: We thank the commenters for their feedback. We note that as a structural measure, OP–17 is limited to evaluating whether or not a provider uses an ONC certified EHR system to track laboratory tests, diagnostic studies, or patient referrals but does not provide information of the impact on outcomes such as diagnosis and treatment. We intend to identify and consider other measures that assess interoperability and care quality for future inclusion in the program as appropriate measures become available. Due to the limitation of OP–17 as a structural measure, we do not believe it is possible to revise it to assess patient outcomes or quality of care directly. Due to the limitations of OP–17, we believe it is appropriate to remove this measure from the Hospital OQR Program.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to remove OP–17 beginning with the CY 2021 payment determination and for subsequent years.

5. Summary of Hospital OQR Program Measure Sets for the CY 2020 and CY 2021 Payment Determinations

In the proposed rule, we did not propose any new measures for the Hospital OQR Program. We refer readers to the CY 2018 OPPS/ASC final rule

with comment period (82 FR 59434 through 59435) for the previously finalized measure set for the CY 2020 payment determination and subsequent years.

The tables below summarize the Hospital OQR Program measure sets as finalized in this final rule with comment period for the CY 2020 and 2021 payment determinations and subsequent years (including previously adopted measures and excluding measures removed in this final rule with comment period).

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Hospital OQR Program Measure Set for the CY 2020 Payment Determination	
NQF #	**Measure Name**
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0289	OP-5: Median Time to ECG†
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-9: Mammography Follow-up Rates
None	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
None	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
0491	OP-17: Tracking Clinical Results between Visits†
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use*
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff***
None	OP-37b: OAS CAHPS – Communication About Procedure***
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery***
None	OP-37d: OAS CAHPS – Overall Rating of Facility***

Hospital OQR Program Measure Set for the CY 2020 Payment Determination	
NQF #	**Measure Name**
None	OP-37e: OAS CAHPS – Recommendation of Facility***

† We note that NQF endorsement for this measure was removed.

* OP-26: Procedure categories and corresponding HCPCS codes are located at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.

** We note that measure name was revised to reflect NQF title.

*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).

**** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

Hospital OQR Program Measure Set for the CY 2021 Payment Determination and Subsequent Years	
NQF #	**Measure Name**
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**

† We note that NQF endorsement for this measure was removed.

º OP-26: Procedure categories and corresponding HCPCS codes are located at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.

* We note that measure name was revised to reflect NQF title.

** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

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6. Hospital OQR Program Measures and Topics for Future Consideration

In the CY 2019 OPPS/ASC proposed rule (83 FR 37188), we requested public comment on future measure topics for the Hospital OQR Program. We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the hospital outpatient setting. The current measure set for the Hospital OQR Program includes measures that assess process of care, imaging efficiency patterns, care transitions, ED throughput efficiency, Health Information Technology (health IT) use, care coordination, and patient safety. Measures are of various types, including those of process, structure, outcome, and efficiency. Through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who receive health care in hospital outpatient settings, while

aligning quality measures across the Medicare program to the extent possible.

We are moving towards greater use of outcome measures and away from use of clinical process measures across our Medicare quality reporting and value-based purchasing programs. We invited public comments on possible measure topics for future consideration in the Hospital OQR Program. We specifically requested comment on any outcome measures that would be useful to add to as well as any process measures that should be eliminated from the Hospital OQR Program.

Comment: Several commenters recommended measure topics for future consideration in the Hospital OQR Program. Commenters' recommendations included: (1) Antibiotic-use related measures to assess inappropriate prescribing; (2) a focus on clinical and population based outcome measures; (3) cancer care measures including two measures related to referral to radiation therapy for both post-breast conserving surgery (NQF 0219) and post-mastectomy (MASTRT); (4) psychiatric care and behavioral health measures; (5) measures identified as meaningful to providers as well patients and their families; (6) rural health measures; (7) measures assessing access to care; (8) measures assessing substance abuse; (9) management of chronic conditions; (10) measures that promote advance care planning and shared-decision making; (11) surgical site infections (SSIs) and medication safety measures such as the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome Measure (NQF #3025) measure; (12) measures using the same unit of analysis that allow comparison between hospitals and ASCs; and, (13) adult immunization measures. Several commenters also supported outcome measures but noted the value of process measures for addressing topics where there is insufficient evidence or standardized data to assess an outcome. One commenter also recommended that CMS consider the recommendations of the 2018 National Quality Forum (NQF) Report titled, ''A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup.'' Another commenter encouraged CMS to recognize composite measures, especially for surgical care, that span across phases of care.

Response: We thank the commenters for their recommendations and suggestions and agree that there are additional high priority topic measurement areas that may be appropriate for the Hospital OQR Program. We will consider the suggested topic areas for future rulemaking and intend to work with stakeholders as we continue to develop the Hospital OQR Program measure set. We thank the commenters for their views and will consider them as we develop future Hospital OQR Program measures and topics.

7. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*. In the proposed rule, we proposed to change the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years and we refer readers to section XIII.D.2. of the proposed rule and this final rule with comment period for more details.

8. Public Display of Quality Measures

We refer readers to the CY 2014 and CY 2017 OPPS/ASC final rules with comment period (78 FR 75092 and 81 FR 79791 respectively) for our previously finalized policies regarding public display of quality measures. In the CY 2019 OPPS/ASC proposed rule (83 FR 37188), we did not propose any changes to our previously finalized public display policies.

C. Administrative Requirements

1. QualityNet Account and Security Administrator

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). In that final rule with comment period, we codified these procedural requirements at 42 CFR 419.46(a). In the CY 2019 OPPS/ASC proposed rule (83 FR 37188), we did not propose any changes to our requirements for the QualityNet account and security administrator.

2. Requirements Regarding Participation Status

In the CY 2019 OPPS/ASC proposed rule (83 FR 37188), we proposed to update our requirements related to the Notice of Participation (NOP) form.

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) for requirements for participation and withdrawal from the Hospital OQR Program. We also codified these procedural requirements at 42 CFR 419.46(a) and (b).

b. Removal of the Notice of Participation (NOP) Form Requirement

We finalized in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109) that participation in the Hospital OQR Program requires that hospitals must: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) complete and submit an online participation form, the Notice of Participation (NOP) form, available at the QualityNet website if this form has not been previously completed, if a hospital has previously withdrawn, or if the hospital acquires a new CMS Certification Number (CCN). In addition, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), we finalized the requirement that that hospitals must submit the NOP according to the below deadlines. These requirements are also codified at 42 CFR 419.46(a).

- If a hospital has a Medicare acceptance date before January 1 of the year prior to the affected annual payment update, the hospital must complete and submit to CMS a completed Hospital OQR Notice of Participation Form by July 31 of the calendar year prior to the affected annual payment update.
- If a hospital has a Medicare acceptance date on or after January 1 of the year prior to the affected annual payment update, the hospital must submit a completed participation form no later than 180 days from the date identified as its Medicare acceptance date.

In the proposed rule (83 FR 37188), beginning with the CY 2018 reporting period/CY 2020 payment determination, we proposed to remove submission of the NOP form as a requirement for the Hospital OQR Program. After reevaluating program requirements, we have concluded that this form does not provide CMS with any unique information, and as such, we believe it is unnecessarily burdensome for

hospitals to complete and submit. In place of the NOP form, we proposed that submission of any Hospital OQR Program data would indicate a hospital's status as a participant in the program. This includes submitting just one data element. That is, hospitals would no longer be required to submit the NOP form as was previously required. Instead, hospitals would need to do the following to be a participant in the Hospital OQR Program: (1) Register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data. We also proposed to update 42 CFR 419.46(a) to reflect these changes.

Comment: A few commenters supported CMS' proposal to remove the NOP as a requirement for the Hospital OQR Program.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposals, as proposed, to no longer require hospitals to submit the NOP form, and update 42 CFR 419.46(a) to reflect these changes.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Payment Determinations

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75110 through 75111) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), we specified our data submission deadlines. We also codified our submission requirements at 42 CFR 419.46(c).

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519 through 70520), where we finalized our proposal to shift the quarters upon which the Hospital OQR Program payment determinations are based, beginning with the CY 2018 payment determination. The finalized deadlines for the CY 2020 payment determination and subsequent years are illustrated in the table below.

CY 2020 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2018 (April 1 - June 30)	11/1/2018
Q3 2018 (July 1 – September 30)	2/1/2019
Q4 2018 (October 1 - December 31)	5/1/2019
Q1 2019 (January 1 - March 31)	8/1/2019

In the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program and made conforming revisions at 42 CFR 419.46(c)(3). In the CY 2019 OPPS/ASC proposed rule (83 FR 37188 through 37189), we did not propose any changes to these policies.

2. Change to the Frequency of Hospital Outpatient Quality Reporting Specifications Manual Release Beginning With CY 2019 and for Subsequent Years

In the CY 2019 OPPS/ASC proposed rule (83 FR 37189), we proposed to change the frequency of the Hospital Outpatient Quality Reporting Specifications Manual release beginning with CY 2019 and for subsequent years. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766 through 68767), we established a subregulatory process for making updates to the measures we have adopted for the Hospital OQR Program. As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), we believe that a measure can be updated through this subregulatory process provided it is a nonsubstantive change. We expect to continue to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to measures based upon changes to guidelines upon which the measures are based.

For a history of our policies regarding maintenance of technical specifications for quality measures, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60631), the CY 2011 OPPS/ASC final rule with comment period (75 FR 72069), and the CY 2013 OPPS/ASC final rule with comment period (77 FR 68469 through 68470). In the proposed rule, we noted that we will continue to use rulemaking to adopt substantive updates to measures we have adopted for the Hospital OQR Program. We believe that this policy adequately balances our need to incorporate nonsubstantive updates to Hospital OQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also noted that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

As stated in CY 2014 OPPS/ASC final rule with comment period (78 FR 75091), under current policy, technical specifications for the Hospital OQR Program measures are listed in the Hospital Outpatient Quality Reporting Specifications Manual, which is posted on the CMS QualityNet website at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228772438492*. We maintain the technical specifications for the measures by updating this Hospital Outpatient Quality Reporting Specifications Manual and including detailed instructions and calculation algorithms. In some cases where the specifications are available elsewhere, we may include links to websites hosting technical specifications. These resources are for hospitals to use when

collecting and submitting data on required measures. We revise the Hospital Outpatient Quality Reporting Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary. We generally release the Hospital Outpatient Quality Reporting Specifications Manual every six months and release addenda as necessary. This release schedule provides at least three months of advance notice for nonsubstantive changes such as changes to ICD–10, CPT, NUBC, and HCPCS codes, and at least six months of advance notice for changes to data elements that would require significant systems changes (78 FR 75091).

However, we believe that unnecessarily releasing two manuals a year has the potential to cause confusion for Hospital OQR Program participants. Therefore, in the proposed rule, we proposed to update the frequency with which we release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of every 6 months, we would release Specifications Manuals every six to 12 months beginning with CY 2019 and for subsequent years. Under this proposal, we would release a Hospital Outpatient Quality Reporting Specifications Manual (Specifications Manual) one to two times per calendar year, depending on the need for an updated release and consideration of our policy to provide at least six months' notice for substantive changes.

Comment: Several commenters supported CMS' proposal to release the Specifications Manual less frequently than every six months. However, a few commenters noted that ad hoc timing for release of the Specifications Manual may be confusing and recommended that CMS release the Specifications Manual once annually. One commenter requested that CMS notify hospitals and vendors about whether or not there will be an update on a 6-month schedule, even if the Specifications Manual is only released every 12 months.

Response: We thank the commenters for their support. We clarify that under our proposal, we would release a full manual once or twice a year, depending on need, as well as any addenda as necessary. Addenda would include discrete updates and do not constitute full manual releases. We acknowledge that ad hoc specifications manual releases could be confusing. After considering public comments and in an effort to provide greater consistency, we are modifying our proposal that we would release a Hospital Outpatient Quality Reporting Specifications Manual one to two times per calendar year; instead, we are finalizing that we will release a full manual once every 12 months and release any addenda as necessary. This reduces manual releases from one to two times per year as proposed, to consistently only once a year. Specifications manuals and addenda will be provided via QualityNet.

After consideration of the public comments we received, we are finalizing a modification of our proposal, beginning with CY 2019 and for subsequent years, to release Specifications Manuals every six to 12 months, such that we will instead release a manual once every 12 months and release addenda as necessary.

3. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. In the CY 2019 OPPS/ASC proposed rule (83 FR 37189), we did not propose any changes to our policies regarding the submission of chart-abstracted measure data where patient-level data are submitted directly to CMS.

We note that, in section XIII.B.4.b.(2)(a) of this final rule with comment period, we are finalizing our proposal to remove OP–5: Median Time to ECG for the CY 2021 payment determination and subsequent years. Therefore, the following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2021 payment determination and subsequent years:

- OP–2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP–18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- OP–23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

4. Claims-Based Measure Data Requirements for the CY 2020 Payment Determination and Subsequent Years

In the CY 2019 OPPS/ASC proposed rule (83 FR 37189 through 37191), we proposed to extend the reporting period [146] for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.

a. General

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75111 through 75112) for a discussion of the general claims-based measure data submission requirements for the CY 2015 payment determination and subsequent years. In the proposed rule, we did not propose changes to our general requirements for claims-based measure data but refer readers to the section below for discussion regarding our proposal specific to OP–32.

We note that, in section XIII.B.4.b. of the proposed rule, we proposed to remove OP–9: Mammography Follow-up Rates, OP–11: Thorax CT Use of Contrast Material, and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT for the CY 2021 payment determination and subsequent years. As discussed in section XIII.B.4.b. of this final rule with comment period, we are finalizing the removals of all of these measures as proposed. Accordingly, the following previously finalized Hospital OQR Program claims-based measures will be required for the CY 2021 payment determination and subsequent years:

- OP–8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP–10: Abdomen CT—Use of Contrast Material;
- OP–13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP–35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

[146] We note that we previously referred to these reporting periods as ''collection periods'' (for example, 82 FR 59440); we now use the term ''reporting period'' in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance (value-based purchasing) programs.

b. Extension of the Reporting Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66949), we finalized the adoption of OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the Hospital OQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66950). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from two calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66955). We finalized a 1-year reporting period, as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes and explained that we would continue to assess this during the dry run (79 FR 66955).

We noted we would complete a dry run of the measure in 2015 using three or four years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66953). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of one year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[147] Consistent with the original measure specifications as described in the 2014 technical report,[148] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[149]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of providers to each other. During subsequent analysis of the 1-year period July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient but did result in lower reliability and decreased precision compared to these measures calculated from longer reporting periods (two or three years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[150] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012–June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to three years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when three years of data are used rather than one year of data.

Using three years of data, compared to just one year, is estimated to increase the number of HOPDs with eligible cases for OP–32 by 5 percent, adding approximately 235 additional facilities to the measure calculation. Facilities reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to three years from one year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to two years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing three years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to two years.

Therefore, we proposed to change the reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for facilities would not change, because this is a claims-based measure. However, with a 3-year reporting period, the most current year of data would be supplemented by the addition of two prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus 2 prior years of data (CYs 2016 and 2017). In the proposed rule, we noted that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare fee-for-service claims from January 1, 2016 to December 31, 2016 to calculate measure scores, which have been previously previewed by facilities and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use three years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

[147] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[148] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[149] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[150] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

	CY 2020 Payment determination	CY 2021 Payment determination	CY 2022 Payment determination
Public display	January 2020	January 2021	January 2022
Reporting period	January 1, 2016 – December 31, 2018	January 1, 2017 – December 31, 2019	January 1, 2018 – December 31, 2020

We refer readers to section XIV.D.4.b. of the proposed rule, where we discussed a similar proposal under the ASCQR Program.

Comment: Several commenters supported CMS' proposal to extend the reporting period for OP–32. A few commenters supported a 3-year reporting period, noting that the extension will mirror the Alternative Payment Model (APM) being presented by ACEP to the Payment Model Technical Advisory Committee (PTAC) and urged CMS to seek stakeholder feedback on developing a methodology and releasing a methodology report for public review and comment.

Response: We thank the commenters for their support for extending the reporting period for OP–32. Regarding the request to release a methodology report, we note that a methodology already exists. We publish annual updates and measures specifications reports, which is a description of the measure updates and measure results from reevaluation and includes detailed measure specifications.[151] This report describes the measure methodology for a given reporting period. We encourage stakeholders to submit comments on the measure's methodology via the Outpatient and ASC Question and Answer tool, *https://cms-ocsq.custhelp.com/*.

Comment: One commenter supported a 2-year reporting period, specifically stating that the priority should be giving beneficiaries critical information they can use today; two years of data typically yields the best mix of reliability and predicting performance today; the larger increase in reliability occurs between one and two years; and the face validity for the measure is poor when using three years of data.

Response: A 3-year reporting period substantially improves the reliability of the measure, as described above. Using a 1-year reporting period, we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs, and for a 2-year reporting period 0.81 for ASCs and 0.67 for HOPDS. However, the median facility-level reliability was highest for both ASCs and HOPDs using a 3-year reporting period: 0.87 for ASCs and 0.75 for HOPDs. In addition, we note that using a 3-year reporting period does not affect the timeliness of our ability to report on this measure, as the data being used have already been collected. Specifically, we note that the most current year of data would be supplemented by the addition of two prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus two prior years of data (CYs 2016 and 2017).

Comment: A few commenters did not support CMS' proposal to extend the reporting period for OP–32, and stated that the five percent increase in the number of HOPDs with eligible cases given the extension in the reporting period is not substantial enough, given that a 3-year reporting period makes the data impractical and meaningless to inform quality improvement efforts and may not reflect system improvements put in place at later dates to comply with new measures.

Response: While extending the measure to include three years of data does increase the number of facilities that can be reported on, the main intent of increasing the reporting period to three years is to increase measure reliability, as described above.

Comment: One commenter provided general feedback on the measure not specifically related to the proposed extension of the reporting period for OP–32. This commenter suggested the measure methodology be updated to exclude diagnosis codes and/or procedures that are obviously indicative of an unforeseen and/or unrelated event.

Response: We measure all-cause hospital visits to encourage OPDs and ASCs to minimize all types of risks that may lead to the need for a hospital visit after a colonoscopy. Measuring only hospital visits that are potentially related to a colonoscopy, such as gastrointestinal bleeding, would limit the measure's impact on quality improvement efforts. Measuring all-cause patient outcomes encourages facilities to minimize the risk of a broad range of outcomes, including the risk of dehydration, pain, dizziness, and urinary retention. These are common problems that may be related or unrelated to a recent colonoscopy. We have structured the measure so that OPDs and ASCs that most effectively minimize patient risk of these outcomes will perform better.

After consideration of the public comments we received, we are finalizing our proposal, as proposed, to change the reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination and for subsequent years. We refer readers to section XIV.D.4.b. of this final rule with comment period, where we are finalizing a similar policy under the ASCQR Program.

5. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. In the CY 2019 OPPS/ASC proposed rule (83 FR 37191), we did not propose any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

6. Data Submission Requirements for Previously Finalized Measures for Data Submitted via a Web-Based Tool for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment

[151] Measure Methodology. Colonoscopy measure. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775197506*.

period (78 FR 75112 through 75115) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521) and the CMS QualityNet website (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1205442125082*) for a discussion of the requirements for measure data submitted via the CMS QualityNet website for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. In the CY 2019 OPPS/ASC proposed rule (83 FR 37191), we did not propose any changes to our policies regarding the submission of measure data submitted via a web-based tool.

We note that, in section XIII.B.4.b.(1) of the proposed rule, we proposed to remove of OP–27: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination and for subsequent years. Because we are finalizing this removal as proposed, for the CY 2020 payment determination, the following web-based quality measures will be required:

- OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data (via CMS' QualityNet website);
- OP–17: Tracking Clinical Results between Visits (NQF #0491) (via CMS' QualityNet website);
- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website);
- OP–29: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website);
- OP–30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) (via CMS' QualityNet website);
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

Furthermore, we note that in section XIII.B.4.b.(2) of the proposed rule, for the CY 2021 payment determination and subsequent years, we proposed to remove: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use; and OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination and for subsequent years. In section XIII.B.4.b.(2) of this final rule with comment period, we are finalizing the removal of OP–30 as proposed. However, as discussed in section XIII.B.4.b.(2)(a) of this final rule with comment period, we are not finalizing the removal of OP–29 or OP–31. Accordingly, the following web-based quality measures will require data to be submitted via a web-based tool for the CY 2021 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499) (via CMS' QualityNet website);
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) (via CMS' QualityNet website);
- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) (via CMS' QualityNet website); and
- OP–33: External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822) (via CMS' QualityNet website).

7. Population and Sampling Data Requirements for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. In the CY 2019 OPPS/ASC proposed rule (83 FR 37191), we did not propose any changes to our population and sampling requirements for chart-abstracted measures.

8. Hospital OQR Program Validation Requirements

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(e) for our policies regarding validation. In the CY 2019 OPPS/ASC proposed rule (83 FR 37191 through 37192), we did not propose any changes to these policies.

9. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. In the CY 2019 OPPS/ASC proposed rule (83 FR 37192), we did not propose any changes to our ECE policy.

10. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), and 42 CFR 419.46(f) for our reconsideration and appeals procedures. In the CY 2019 OPPS/ASC proposed rule (83 FR 37192), we did not propose any changes to our reconsideration and appeals procedures.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2019 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in

the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this final rule with comment period, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or '''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; the rural sole community hospital adjustment; and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this final rule with comment period.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2019

In the CY 2019 OPPS/ASC proposed rule (83 FR 37193), we proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2019 annual payment update factor. For the CY 2019 OPPS, the proposed reporting ratio was 0.980, calculated by dividing the proposed reduced conversion factor of 77.955 by the proposed full conversion factor of 79.546. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2019 OPPS, we proposed to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than new technology APCs to which we have proposed status indicator assignment of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR

Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements.

We did not receive any public comments on these proposals. For the CY 2019 OPPS, the final reporting ratio is 0.980, calculated by dividing the final reduced conversion factor of 77.900 by the final full conversion factor of 79.490. We also are finalizing the remainder of our proposals regarding the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements for CY 2019 payment determination without modification.

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIII.A.1. of the proposed rule for a general overview of our quality reporting programs and to section I.A.2. of the proposed rule and this final rule with comment period for a discussion of our new Meaningful Measures Initiative.

2. Statutory History of the ASCQR Program

We refer readers to section XIV.K.1. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We seek to promote higher quality and more efficient health care for beneficiaries. This effort is supported by the adoption of widely-agreed-upon quality measures. We have worked with relevant stakeholders to define measures of quality in almost every healthcare setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and outcomes. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of ASC services and to make such information publicly available, we implemented the ASCQR Program. We refer readers to section XV.A.3. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75122), section XIV. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966 through 66987), section XIV. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70526 through 70538), section XIV. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79797 through 79826) and section XIV. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59476) for an overview of the regulatory history of the ASCQR Program.

4. Meaningful Measures Initiative

In the proposed rule, we proposed a number of new policies for the ASCQR Program. We developed these proposals after conducting an overall review of the Program under our new Meaningful Measures Initiative, which is discussed in more detail in section I.A.2. of the proposed rule and this final rule with comment period. The proposals reflected our efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for our beneficiaries while minimizing costs, which can consist of several different types of costs, including, but not limited to: (1) Facility information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS; (2) the facility cost associated with complying with other quality programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). These proposals also reflected our efforts to improve the usefulness of the data that we publicly report in the ASCQR Program. Our goal is to improve the usefulness and usability of CMS quality program data by streamlining how facilities are reporting and accessing data, while maintaining or improving consumer understanding of the data publicly reported on a *Compare* website. We believe this framework will allow ASCs and patients to continue to obtain meaningful information about ASC performance and incentivize quality improvement while also streamlining the measure sets to reduce duplicative measures and program complexity so that the costs to ASCs associated with participating in this program do not outweigh the benefits of improving beneficiary care.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for ASCQR Program quality measure selection. In the CY 2019 OPPS/ASC proposed rule (83 FR 37193), we did not propose any changes to these policies.

2. Accounting for Social Risk Factors in the ASCQR Program

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[152] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing programs.[153] As we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59445 through 59447), ASPE's report to Congress found that, in the context of value-based

[152] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[153] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59446), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[154] The trial period ended in April 2017 and a final report is available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF is now undertaking an extension of the socioeconomic status (SES) trial,[155] allowing further examination of social risk factors in outcome measures.

In the FY 2018 and CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or facility that would also allow for a comparison of those differences, or disparities, across facilities. Feedback we received through our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patients' backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public. We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for facilities to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower beneficiaries and other consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discourage the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to reduce health disparities among patient groups within and across healthcare settings by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously adopted a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years, except when they are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). In the CY 2019 OPPS/ASC proposed rule (83 FR 37194), we did not propose any changes to this policy.

b. Removal Factors for ASCQR Program Measures

(1) Previously Finalized Policy

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969) and 42 CFR 416.320 for a detailed discussion of the process for removing adopted measures from the ASCQR Program. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967 through 66969), we finalized the ASCQR Program measure removal factors[156] for determining whether to remove ASCQR Program measures as follows:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Availability of alternative measures with a stronger relationship to patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

In that final rule with comment period, we stated that the benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis (79 FR 66969). Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor. We noted that in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473), similar measure removal factors were finalized for the Hospital OQR Program.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37194 through 37197), we proposed to: (1) Remove one factor; (2) add two new measure removal factors,

[154] National Quality Forum. Final Report-Disparities Project. September 2017. Available at: *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[155] National Quality Forum. Health Equity Program: Social Risk Initiative 2.0. 2017. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[156] We note that we previously referred to these factors as ''criteria'' (for example, 82 FR 59474 through 59475); we now use the term ''factors'' in order to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay for performance (value-based purchasing) programs.

and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies. We also made one clarification to measure removal Factor 1. These items are discussed in detail below.

(2) Removal of Factor 2

In the CY 2019 OPPS/ASC proposed rule (83 FR 37195), we proposed to remove the ASCQR Program's measure removal Factor 2, availability of alternative measures with a stronger relationship to patient outcomes. We received comments in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66967) remarking on the duplicative nature of the ASCQR Program's measure removal Factor 2, availability of alternative measures with a stronger relationship to patient outcomes, with measure removal Factor 6, the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic. In that final rule with comment period, we stated that ''criterion (2) applies when there is more than one alternative measure with a stronger relationship to patient outcomes that is available, and criterion (6) applies where there is only one measure that is strongly and specifically associated with desired patient outcomes for the particular topic that is available'' (79 FR 66967). Since reevaluating those comments, we have now come to agree that ASCQR measure removal Factor 2 is repetitive with Factor 6. Therefore, we proposed to remove Factor 2, ''availability of alternative measures with a stronger relationship to patient outcomes,'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period. We invited public comment on our proposal as discussed above.

Comment: One commenter supported CMS' proposal to remove measure removal Factor 2, noting its repetitive nature with removal Factor 6.

Response: We thank the commenter for its support.

After consideration of the public comments we received, we are finalizing our proposal to remove measure removal Factor 2, ''availability of alternative measures with a stronger relationship to patient outcomes,'' from the ASCQR Program beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, as proposed.

(3) Addition of Two New Measure Removal Factors

(a) Measure Removal Factor 2

We want the ASCQR Program measure removal factors to be fully aligned with the Hospital OQR Program to provide consistency across these two outpatient setting quality reporting programs. We believe it is important to evaluate the appropriateness of measures across programs using similar standards. In evaluating the two programs' removal factors, we became aware that the Hospital OQR Program includes one factor not currently in the ASCQR Program. The Hospital OQR Program's second measure removal factor specifies ''performance or improvement on a measure does not result in better patient outcomes'' (75 FR 50185).

Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37195), we proposed to add ''performance or improvement on a measure does not result in better patient outcomes'' as the new removal Factor 2 for the ASCQR Program (replacing the previously adopted factor removed above). We believe that this factor is applicable in evaluating the ASCQR Program quality measures for removal because we have found it useful for evaluating measures in the Hospital OQR Program, which also evaluates the outpatient setting. In the proposed rule, we also noted that this proposed factor is already included in the Hospital IQR (80 FR 49641 through 49642), the PCHQR (82 FR 38411), the LTCH QRP (77 FR 53614 through 53615), and the IPFQR (82 FR 38463) Programs. We proposed to add a new removal factor to the ASCQR Program: ''performance or improvement on a measure does not result in better patient outcomes'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period. We invited public comments on our proposal, as discussed above.

Comment: A few commenters supported CMS' proposal to add a new measure removal Factor 2, noting it would align the ASCQR and Hospital OQR Programs and provide consistency for evaluating measures across quality reporting programs.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to add a new removal factor to the ASCQR Program, ''performance or improvement on a measure does not result in better patient outcomes'' beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period, as proposed.

(b) New Measure Removal Factor 8

In the CY 2019 OPPS/ASC proposed rule (83 FR 37195), we proposed to adopt an additional factor to consider when evaluating measures for removal from the ASCQR Program measure set:

- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discuss in section I.A.2. of the proposed rule and this final rule with comment period with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the ASCQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice or payment scoring). It may also be costly for ASCs to track confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

In weighing the costs against the benefits, we evaluate the benefits of the measure as a whole, but in particular, we assess the benefits through the framework of our Meaningful Measures Initiative, as we discussed in section I.A.2. of the proposed rule and this final rule with comment period. One key aspect of patient benefits is assessing the improved beneficiary health

outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted and are illustrated through the Meaningful Measures framework's 6 domains and 19 areas. For example, we assessed the Healthcare Worker Influenza Vaccination and patient Influenza Vaccination measures categorized in the Quality Priority ''Promote Effective Prevention and Treatment of Chronic Disease'' in the meaningful measure area of ''Preventive Care'' across multiple CMS programs, and considered: Patient outcomes, such as mortality and hospitalizations associated with influenza; CMS measure performance in a program; and other available and reported influenza process measures, such as population influenza vaccination coverage.

When these costs outweigh the evidence supporting the benefits to patients with the continued use of a measure in the ASCQR Program, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ASCQR Program is to improve beneficiary outcomes by incentivizing health care facilities to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data (including percentage payment adjustment data) is of limited use because it cannot be easily interpreted by beneficiaries and used to inform their choice of facility. In these cases, removing the measure from the ASCQR Program may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor assessing costs versus benefits on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for ASCs to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We invited public comment on our proposal to adopt an additional measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, beginning with the effective date of the CY 2019 OPPS/ASC final rule with comment period and for subsequent years.

We referred readers to section XIV.B.3.c. of the proposed rule, where we proposed to remove four measures based on this proposed measure removal factor. We noted that we had also proposed this same measure removal factor for the Hospital OQR Program in section XIII.B.4.a.(4) of the proposed rule, as well as for other quality reporting and value-based purchasing programs for FY 2019 including: the Hospital VBP Program (83 FR 41442), the Hospital IQR Program (83 FR 41544); the PCHQR Program (83 FR 41609 through 41610); the LTCH QRP (83 FR 41625 through 41627); the HQRP (83 FR 41625 through 41627); the IRF QRP (83 FR 38556 through 38557); the SNF QRP (83 FR 39267 through 39269); and the IPFQR Program (83 FR 38591 through 38593).

Comment: Several commenters supported CMS' proposal to add measure removal Factor 8, and noted that it will allow CMS to reduce cost and burden, promote alignment of measure removal criteria across quality reporting programs and the Meaningful Measures Initiative, and allow providers to focus on improving care.

Response: We thank the commenters for their support.

Comment: A few commenters opposed CMS' proposal to add measure removal Factor 8. A few commenters requested clarification on the types of costs that CMS will consider and requested transparency in the process of evaluation in the costs and benefits of measures. One commenter expressed concern that the costs described under measure removal Factor 8 are not defined. One commenter noted the costs with changing measures to facilities, providers, and measure developers. Another commenter expressed concern that CMS may deem a measure too costly to implement, while providers and patients may continue to find it meaningful. Commenters also recommended direct and indirect costs that CMS may consider in evaluating measures under measure removal Factor 8. These costs included those associated with: (1) Measures that require data collection from multiple data sources, rather than just one; (2) contracting with vendors; (3) tracking performance and investing in resources for quality improvement. One commenter stated it would oppose the new factor unless costs and benefits are defined as only costs and benefits to beneficiaries and the public.

Response: As noted in the proposed rule (83 FR 37193), we have defined costs, for the purpose of evaluating measures under measure removal Factor 8, as including, but not limited to: (1) Facility information collection burden and related costs and burden associated with the submission/reporting of quality measures to CMS; (2) the facility cost associated with complying with other programmatic requirements; (3) the facility cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the CMS cost associated with the program oversight of the measure including measure maintenance and public display; and (5) the facility cost associated with compliance with other federal and/or State regulations (if applicable). This was not intended to be a complete list of the potential factors to consider in evaluating measures. In addition, as we apply this measure removal factor in future rulemaking, we will describe our rationale for the removal of a measure and will include the costs and benefits we considered.

We thank commenters for their suggestions regarding additional costs to consider. We will use this feedback, as well as input from all stakeholders, as we apply measure removal Factor 8 in future rulemaking.

With respect to the commenter that suggested that costs and benefits should be defined as only costs and benefits to beneficiaries and the public, we believe that various stakeholders may have different perspectives on how to define costs as well as benefits. Because of these challenges, we intend to evaluate costs and benefits for each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: Patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining any specific measure in the ASCQR Program. However, we believe that while a measure's use in the ASCQR Program may benefit many entities, the primary benefit is to patients and their caregivers through incentivizing high-quality care and providing publicly reported data regarding the quality of care available. We note that we intend to assess the costs and benefits to program stakeholders, including but not limited to, those listed in the proposed rule. Therefore, we intend to consider the benefits, especially those to patients and their families, when evaluating measures under this measure removal factor. As noted above, we have offered

a definition of costs. However, this was not intended to be a complete list of the potential factors to consider in evaluating measures and we intend to consider additional examples of cost described in public comment, including the costs and benefits to beneficiaries and the public, as recommended above.

Comment: A few commenters recommended that CMS seek input from hospitals, physicians, and other stakeholders when evaluating the costs and benefits of quality reporting.

Response: We thank the commenters for their feedback and note that we will consider stakeholder input when evaluating both the costs of quality reporting as well as the benefits of collecting and reporting quality data. As stated above, we intend to evaluate costs and benefits for each measure on a case-by-case basis, while considering input from a variety of stakeholders, including, but not limited to: patients, caregivers, patient and family advocates, providers, provider associations, healthcare researchers, healthcare purchasers, data vendors, and other stakeholders with insight into the direct and indirect benefits and costs (financial and otherwise) of maintaining any specific measure in the ASCQR Program.

Comment: A few commenters recommended that CMS consider measure sets as a whole and the consistency of quality reporting program measure sets. Another commenter recommended that when a measure is removed under Factor 8 that it should be replaced by a measure that is easier to implement and aimed at improving care within the same measure domain to avoid gaps in the measure set. One commenter further recommended that measure sets should include actionable process measures that contribute to the outcomes being measured.

Response: We intend to continue to develop a robust measure set for the ASCQR Program and appreciate the commenters' feedback. We consider the measure set as a whole, the types of measures in the measure set, and the consistency throughout quality reporting programs, among other things, when assessing measures in the ASCQR Program. We continually seek ways to improve the ASCQR Program measure set, including through identification of more efficient means of capturing data. Retaining a strong measure set that addresses critical quality issues is one benefit that we would consider in evaluating whether a measure should be potentially removed from the ASCQR Program measure set. In addition, we note that in this final rule with comment period, as discussed in more detail further below, we are not finalizing our proposals below to remove two measures (ASC–9 and ASC–11) under Factor 8 in part to maintain a more balanced and cohesive ASCQR Program measure set.

After consideration of the public comments we received, we are finalizing our proposal to adopt measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, for the ASCQR Program beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, as proposed.

As a result of the finalization of our proposals to remove one and add two new removal factors as proposed, the new measure removal factors list for the ASCQR Program consists of the following:

- Factor 1. Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

(4) Revisions to 42 CFR 416.320(c)

In the CY 2019 OPPS/ASC proposed rule (83 FR 37196), we proposed to revise 42 CFR 416.320(c) to better reflect our considerations for removing measures policy in light of the above proposals.

We did not receive any comments on our proposal. Therefore, we are finalizing our proposal to revise 42 CFR 416.320(c), as proposed.

(5) Clarification for Removal Factor 1: ''Topped-Out'' Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period where we finalized the criteria for determining when a measure is ''topped-out'' (79 FR 66968). In that final rule with comment period, we finalized two criteria for determining when a measure is ''topped-out'' under the ASCQR Program: (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10 (79 FR 66968 through 66969).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37196), we did not propose any changes to this policy; however, we clarified our process for calculating the truncated coefficient of variation (TCOV) for four of the measures (ASC–1, ASC–2, ASC–3, and ASC–4) proposed for removal from the ASCQR Program. Utilizing our finalized methodology (79 FR 66968), we determine the truncated coefficient of variation (TCOV) by calculating the truncated standard deviation (SD) divided by the truncated mean. As discussed above, our finalized removal criteria state that to be considered ''topped-out,'' a measure must have a TCOV of less than 0.10. We utilize the TCOV because it is generally a good measure of variability and provides a relative methodology for comparing different types of measures.

Unlike the majority of our measures, for which a higher rate (indicating a higher proportion of a desired event) is the preferred outcome, some measures—in particular, ASC–1, ASC–2, ASC–3, and ASC–4—assess the rate of rare, undesired events for which a lower rate is preferred. For example, ASC–1 assesses the occurrence of patient burns, a patient safety issue. However, when determining the TCOV for a measure assessing rare, undesired events, the mean, or average rate of event occurrence, is very low and the result is a TCOV that increases rapidly and approaches infinity as the proportion of rare events declines.[157] We note that the SD, the variability statistic, is the same in magnitude for measures assessing rare and non-rare events.

In the proposed rule, we proposed to remove a number of measures that assess the rate of rare, undesired events for which a lower rate is preferred—ASC–1, ASC–2, ASC–3, and ASC–4—and referred readers to section XIV.B.3.c. of the proposed rule where these proposed measure removals are discussed in detail. Because by design

[157] Rose-Hulman Institute of Technology. Denominator approaching zero. Retrieved from: *https://www.rose-hulman.edu/media/89584/lclimitsguide.pdf.*

these measures have maintained very low rates (indicating the preferred outcome), we utilized the mean of *non-adverse* events in our calculation of the TCOV. For example, for ASC–1, to calculate the TCOV we divide the SD by the average rate of patients *not* receiving burns (1 minus the rate of patients receiving burns) rather than the rate of patients receiving burns. Utilizing this methodology results in a TCOV that is comparable to that calculated for other measures and allows us to assess rare-event measures by still generally using our previously finalized topped-out criteria.

c. Removal of Quality Measures From the ASCQR Program Measure Set

In the CY 2019 OPPS/ASC proposed rule (83 FR 37197 through 37202), we proposed to remove a total of eight measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations. Specifically, beginning with the CY 2020 payment determination, we proposed to remove: (1) ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and beginning with the CY 2021 payment determination, we proposed to remove: (2) ASC–1: Patient Burn (NQF #0263); (3) ASC–2: Patient Fall (NQF #0266); (4) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (5) ASC–4: All-Cause Hospital Transfer/Admission (NQF #0265); (6) ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (7) ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659); and (8) ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). We proposed to remove these measures under the following measure removal factors: Factor 1—measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures); and Factor 8—the costs associated with a measure outweigh the benefit of its continued use in the program.

We are finalizing the removal of two measures out of the eight measure removals we proposed. The proposed measure-specific removals are discussed in detail further below. However, because we received several general comments regarding all eight proposals as a whole, we are discussing those first.

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program measure set. Some of these commenters noted that the proposals will reduce burden, simplify facility reporting, and reduce duplication. One commenter suggested that CMS remove all eight measures beginning with CY 2020, rather than delaying removal of seven measures until CY 2021. Some commenters agreed with CMS' rationale for removals and noted that topped-out or not beneficial measures should be removed as soon as possible.

Response: We thank the commenters for their support for our proposed measure removals. However, data collection and reporting for the CY 2020 payment determination already began in January 2018 for all eight of the measures proposed for removal. Thus, by the effective date of this final rule with comment period, facilities will have already collected 11 months of data for the CY 2020 payment determination. In consideration of facilities' efforts already exerted, we are finalizing removal of these measures starting with the next proximate payment determination.

Comment: One commenter opposed CMS' proposal to remove measures from the ASCQR Program, citing its belief that consumers should be offered more quality information, rather than less, that can be used in selecting facilities. Another commenter recommended that CMS maintain the existing measure set and work to reduce provider burden through alignment across programs instead.

Response: We thank the commenters for their feedback and note our agreement that consumers should be provided with as much valuable quality information as possible. As described in the proposed rule, we proposed to remove some measures because the costs associated with a measure outweigh the benefit of its continued use in the program and measure performance among facilities is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures). We have identified these and other measure removal factors specifically to ensure that the data provided to consumers is meaningful and valuable. We do not believe it is beneficial to maintain program measures indefinitely. However, we agree that burden should be reduced through program alignment and will continue to seek opportunities to do this. In the proposed rule, we proposed several policies to align with the Hospital OQR Program including updating our measure removal factors and removing OP–27 and ASC–8, OP–29 and ASC–9, OP–30 and ASC–10, and OP–31 and ASC–11, and we are finalizing several of these aligned proposals in this final rule with comment period.

(1) Measure Removal for the CY 2020 Payment Determination and Subsequent Years—ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel

For the CY 2020 payment determination and subsequent years, we proposed to remove one NHSN measure under proposed measure removal Factor 8, the costs associated with this measure outweigh the benefit of its continued use in the program.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74510), where we adopted ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), beginning with the CY 2016 payment determination and for subsequent years. This process of care measure, also a National Healthcare Safety Network (NHSN) measure, assesses the percentage of healthcare personnel who have been immunized for influenza during the flu season. We initially adopted this measure based on our recognition that influenza immunization is an important public health issue and vital component to preventing healthcare associated infections. We believe that the measure addresses this public health concern by assessing influenza vaccination in the ASC among healthcare personnel (HCP), who can serve as vectors for influenza transmission.

In the proposed rule, we proposed to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel beginning with the CY 2020 payment determination under proposed measure removal Factor 8, because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program.

The information collection burden for the Influenza Vaccination Coverage Among Healthcare Personnel measure is less than for measures that require chart abstraction of patient data because influenza vaccination among health care personnel can be calculated through review of records maintained in administrative systems and because facilities have fewer health care personnel than patients. As such, ASC–8 does not require review of as many records. However, this measure does still pose information collection burden on facilities due to the requirement to identify personnel who have been

vaccinated against influenza and for those not vaccinated, the reason why.

Furthermore, as we stated in section XIV.B.3.b. of the proposed rule, costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For example, it may be costly for health care providers to maintain general administrative knowledge to report these measures. In addition, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

In our analysis of the ASCQR Program measure set, we recognized that some ASCs face challenges with respect to the administrative requirements of the NHSN in their reporting of the Influenza Vaccination Coverage Among Healthcare Personnel measure. These administrative requirements (which are unique to NHSN) include annually completing NHSN system user authentication. Enrolling in NHSN is a five-step process that the CDC estimates takes an average of 263 minutes per ASC.[158] Furthermore, submission via NHSN requires the system security administrator of participating facilities to re-consent electronically, ensure that contact information is kept current, ensure that the ASC has an active facility administrator account, keep Secure Access Management Service (SAMS) credentials active by logging in approximately every two (2) months and changing their password, create a monthly reporting plan, and ensure the ASC's CCN information is up-to-date.

Unlike short-term acute care hospitals which participate in other quality programs, such as the Hospital IQR and HAC Reduction Programs, ASCs are only required to participate in NHSN to submit data for this one measure. This may unduly disadvantage smaller ASCs, specifically those that are not part of larger hospital systems, because these ASCs do not have NHSN access for other quality reporting or value-based payment programs. It is our goal to ensure that the ASCQR Program is equitable to all ASCs and this measure may disproportionately affect small, independent ASCs. Especially for these small, independent ASCs, the incremental costs of this measure, as compared to other measures in the ASCQR Program measure set, are significant because of the requirements imposed by NHSN participation.

We continue to believe that the Influenza Vaccination Coverage Among Healthcare Personnel measure provides the benefit of protecting ASC patients against influenza. However, we believe that these benefits are offset by other efforts to reduce influenza infection among ASC patients, such as numerous healthcare employer requirements for healthcare personnel to be vaccinated against influenza.[159] [160] We also expect that a portion of MIPS-eligible clinicians nationwide will report on the Preventive Care and Screening: Influenza Immunization measure (NQF #0041) through the Quality Payment Program (QPP).[161] Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure. CMS remains responsive to the public health concern of influenza infection within the Medicare FFS population by collecting data on rates of influenza immunization among patients.[162] Thus, the public health concern is addressed via these other efforts to track influenza vaccination. The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area. In addition, as we discussed in section XIV.B.3.b. of the proposed rule, where we proposed to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

We wish to minimize the level of cost of our programs for participating facilities, as discussed under the Meaningful Measures Initiative described in section I.A.2. of the proposed rule and this final rule with comment period. In our assessment of the ASCQR Program measure set, we prioritized measures that align with this Framework as the most important to the ASC population. Our assessment concluded that while the Influenza Vaccination Coverage Among Healthcare Personnel measure continues to provide benefits, these benefits are diminished by other factors and are outweighed by the costs and burdens of reporting this measure.

For these reasons, we proposed to remove ASC–8: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) from the ASCQR Program beginning with the CY 2020 payment determination and for subsequent years because the costs associated with the measure outweigh the benefit of its continued use in the program. We noted that if proposed measure removal Factor 8 is not finalized, removal of this measure would also not be finalized. We also noted that a similar measure was also proposed for removal from the Hospital OQR Program in section XIII.B.4.b.(1) of the proposed rule and the IPFQR Program in the FY 2019 IPF PPS proposed rule (83 FR 21104). We invited public comments on our proposal to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel from the ASCQR Program beginning with the CY 2020 payment determination under measure removal Factor 8, because we have concluded that the costs associated with this measure outweigh the benefit of its continued use in the program, as discussed above.

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program. Many commenters specifically supported CMS' proposal to remove ASC–8 because the costs of the measure outweigh its continued use in the ASCQR Program. One commenter remarked that while immunization is a critical component of preventing influenza transmission, that many employer-based programs and requirements already promote vaccination. Another commenter noted that many ASCs may fail to receive the APU due to failing to submit data related to ASC–8.

Response: We thank the commenters for their support.

Comment: A few commenters noted that the NHSN website is very burdensome and it is difficult for ASCs to keep their accounts active when it utilized only once per year. One commenter noted that keeping such accounts active may be particularly difficult for ASCs that are not part of a hospital system. A few commenters recommended that the measure could be redeveloped and submitted via QualityNet in the future.

Response: We thank the commenters for their support and agree that ASCs face an undue burden from registering and maintaining access to the CDC's NHSN system for this one measure as compared to other quality reporting programs that require access for several

[158] Available at: *https://www.cdc.gov/nhsn/ambulatory-surgery/enroll.html* (the estimates for time to complete are 2 hours 45 minutes for step 1, 10 minutes for step 2, 16 minutes for step 3a, 35 minutes for step 3b, 32 minutes for step 4, and 5 minutes for step 5; totaling 263 minutes).

[159] CDC, Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[160] CDC Influenza Vaccination Coverage Among Health Care Personnel—United States, 2013–14 Influenza Season. Available at: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm.*

[161] QPP 2017 Measures Selection: Influenza. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

[162] Ibid.

healthcare safety measures. We will continue to assess the ASCQR Program measure set and will consider future measures, including the potential for a re-developed measure submitted via QualityNet that addresses influenza vaccinations for health care workers, as part of our goal to maintain a robust measure set.

Comment: One commenter stated that although the process to register on NHSN is tedious, that it is not impossible and that reporting on the site is easy. Another commenter noted that the burden to submit the measure via NHSN is minimal once the data is collected and that having ASCs participate in NHSN reporting will provide benefit as new measures are developed in partnership with the CDC.

Response: We thank the commenters for their input. We remain concerned that the burden of reporting this measure is greater for ASCs compared to the relative burden for hospitals participating in the Hospital IQR and HAC Reduction Programs. The entire burden of registering for and maintaining access to the CDC's NHSN system for ASCs, especially independent or freestanding ASCs, is due to this one measure; whereas hospitals paid under the IPPS, participating in the Hospital IQR Program, the HAC Reduction Program and the Hospital VBP Program, for example, must register and maintain NHSN access for several healthcare safety measures, not just one. However, we note that, beyond the ASCQR Program, facilities may independently choose to voluntarily report data to NHSN on vaccination rates using the NHSN Healthcare Personnel Safety Component.

Comment: Several commenters opposed CMS' proposal to remove ASC–8 from the ASCQR Program. A few commenters expressed concern that influenza is a critical public health issue and that influenza vaccination coverage of healthcare workers helps create a safe environment for patients, visitors, and employees. A few commenters expressed concern that removal of ASC–8 would result in lower vaccination rates among healthcare workers. A few commenters noted that the Medicare population may be more susceptible to vaccine preventable illnesses such as influenza.

Response: We agree that influenza vaccination for both patients and healthcare personnel is important in the ASC setting, as well as other healthcare settings, and we believe that these two activities are both intended to address the public health concern of reducing influenza infection.

However, while we agree that Medicare beneficiaries may have additional risk of contracting influenza, as noted in our proposal, we believe the effects of removing this measure from the ASCQR Program are mitigated as the issue is addressed in other initiatives such as State laws and employer programs that require influenza vaccination of healthcare workers.[163] [164] Because of this, we do not believe that retaining this measure would result in lower rates of vaccination coverage among healthcare personnel. Further, we have retained the measure in the Hospital IQR Program (83 FR 41579), thus, requiring reporting in the short-term, acute care hospital setting. In addition, we believe that the burden of this measure on ASCs, especially independent or freestanding ASCs, outweighs the limited benefit of addressing this topic again under the ASCQR Program in addition to the many other vaccination initiatives.

Comment: A few commenters stated that ASC–8 plays a critical role in the CMS Quality Strategy and the National Quality Strategy in terms of immunization efforts. A few commenters stated that removal of the measure would create greater inconsistency across quality reporting programs.

Response: We agree that influenza is a critical public health issue that is part of the CMS Quality Strategy and the National Quality Strategy. Through our Meaningful Measures Initiative, it is our goal to ensure that we are addressing high-impact measure areas that safeguard public health while minimizing the level of burden for providers and suppliers. We continue to believe in the importance of influenza vaccination coverage for health care workers, particularly in acute care settings, and have retained this measure in the Hospital IQR Program (83 FR 41579) in order to address this concern.

As we noted above, the burden of reporting this measure is greater for ASCs compared to the relative burden for hospitals participating in the Hospital IQR and HAC Reduction Programs. The entire burden of registering for and maintaining access to the CDC's NHSN system for ASCs, especially independent or freestanding ASCs, is due to this one measure; whereas, hospitals paid under the IPPS, participating in the Hospital IQR Program, the HAC Reduction Program, and the Hospital VBP Program, for example, must register and maintain NHSN access for several healthcare safety measures, not just one.

Comment: One commenter stated that the cost associated with mitigating an influenza outbreak outweighs the cost of retaining ASC–8 in the ASCQR Program.

Response: As noted above, because this issue is addressed in other initiatives at the State-level and through employers, we do not believe it would result in lower rates of vaccination coverage among healthcare personnel in ASCs or increase the risk of an outbreak.

After consideration of the public comments we received, we are finalizing our proposal to remove ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel from the ASCQR Program beginning with the CY 2020 payment determination, as proposed.

(2) Measure Removals for the CY 2021 Payment Determination and Subsequent Years

For the CY 2021 payment determination and subsequent years, we proposed to remove: (1) Four claims-based measures under measure removal Factor 1, ''topped-out'' status; as well as (2) two chart-abstracted measures and (3) one web-based tool measure under proposed measure removal Factor 8.

(a) Proposals To Remove Measures Under Removal Factor 1: ASC–1, ASC–2, ASC–3, and ASC–4

In the proposed rule, beginning with the CY 2021 payment determination and subsequent years, we proposed to remove ASC–1, ASC–2, ASC–3, and ASC–4 under measure removal Factor 1, measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. The ASCQR Program previously finalized two criteria for determining when a measure is ''topped-out'': (1) When there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation is less than or equal to 0.10 (79 FR 66968 through 66969). In the proposed rule, we referred readers to section XIV.B.3.b. of the proposed rule, where we clarified and discussed how we calculate the TCOV for measures that assess the rate of rare, undesired events for which a lower rate is preferred, such as ASC–1, ASC–2, ASC–3, and ASC–4.

[163] CDC. Influenza Vaccination Information for Health Care Workers. Available at: *https://www.cdc.gov/flu/healthcareworkers.htm.*

[164] CDC Influenza Vaccination Coverage Among Health Care Personnel—United States, 2013–14 Influenza Season. Available at: *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm.*

For each of these measures, we stated that we believed that removal from the ASCQR Program measure set is appropriate as there is little room for improvement. In addition, removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we stated that we believed the burden associated with reporting these measures outweighs the benefits of keeping them in the program.

We also note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination, but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for the measures begins during CY 2018 for the CY 2020 payment determination. Each measure is discussed in more detail further below. However, because we received several general comments regarding these proposals as a whole, we are discussing those first.

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program. Several commenters specifically supported the removal of ASC–1, ASC–2, ASC–3, and ASC–4.

Response: We thank the commenters for their support.

Comment: Several commenters opposed CMS' proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4, noting that although the measures are topped-out, that these measures provide important data for facilities and patients. A few commenters noted that they measure rare events for which the occurrence should be zero and that the measures should not be eliminated in order to continue to prevent and detect these types of occurrences. One commenter stated that measures should not be removed from the program based solely on topped-out status. This commenter recommended that CMS ensure the measure is topped-out for a number of years, evaluate whether there are unintended consequences of removal, and continue monitoring performance on topped-out safety measures. Another commenter expressed concern that variation in measure performance exists between high and low performing States. Another commenter was concerned that if the measures are removed that there may be no other national-level data sources about the quality of care that is being provided in ASCs, and another added that private insurers have started using them as well. Another commenter believed that these measures are crucial because they are applicable to all ASCs and was concerned that there are no other measures in the ASCQR Program that are reported by all ASCs.

Response: We thank the commenters for their feedback. The ASCQR Program finalized the ''topped-out'' methodology to evaluate variation in performance among ASCs (79 FR 66968) consistent with other quality reporting and value-based programs, including the Hospital OQR (79 FR 66769), Hospital IQR (80 FR 49641 through 49643), Hospital VBP (79 FR 50055), IPFQR (82 FR 38463 through 38465), and PCHQR (81 FR 57182 through 57183) Programs. Our topped-out methodology does not evaluate variation at the State level, but rather at the level of individual ASCs. Our analyses demonstrate that the variation in performance among ASCs for these measures is statistically indistinguishable. As shown in the tables provided for each proposal, facilities have a rate of 100 percent performance at both the 90th and 75th percentiles for the past five years of reporting.

Due to public comments, we have reevaluated our data. In the proposed rule, we believed that the measures' performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made and that the measures met the criteria for being topped-out. However, we have reviewed many studies, in addition to the public comments we received, that show the importance of measuring and reporting the data for these measures, as discussed in each proposal below. Therefore, we have now come to believe that these measures may be more valuable to stakeholders than we initially perceived in the proposed rule. We agree that it is important to continue to monitor these types of events considering the potential negative impacts to patients' morbidity and mortality, in order to continue to prevent their occurrence and ensure that they remain rare. We acknowledge that these measures provide critical data to beneficiaries and further transparency for care provided in the ASC setting that would be useful in choosing an ASC for care, and that these measures are valuable to the ASC community. Despite little room for improvement, these measures provide beneficiaries and ASCs with vital information about patient burns, patient falls, wrong site, wrong side, wrong patient, wrong procedure, wrong implant events, and hospital transfers/admissions that take place in the ASC setting and we believe it would be prudent to keep them in the program at this time in order to continue to detect and prevent these events. Further, we acknowledge that having measures that apply to all ASCs provides beneficiaries with the most comprehensive patient safety data to use when making decisions about a site of care. ASC–1, ASC–2, ASC–3, and ASC–4 are measures for which all ASCs, regardless of specialty area, can submit data in contrast to other measures, such as ASC–14: Unplanned Anterior Vitrectomy, which would only apply to ASCs where specialty-specific procedures are performed, such as ophthalmology procedures in the case of ASC–14. Therefore, we are not finalizing our proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4. These measures will remain in the program under our measure retention policies, unless we take future action under our measure removal policies.

Comment: A few commenters who opposed the removal of these measures were also concerned about the data submitted for them. One commenter expressed concern that only 50 percent of claims are required to have QDCs and questioned how some ASCs are able to report that no errors occurred in their facilities. Another commenter was concerned about the proportion of ASCs that had missing data for these measures, noting that the missing data would affect their eligibility to receive the APU, but does not impact their status as a Medicare provider. Another commenter was concerned about under-reporting and recommended that CMS conduct data validation studies and empirical analyses of these measures, particularly for ASC–1, ASC–2, and ASC–3. This commenter also recommended that the denominator for ASC–1, ASC–2, and ASC–3 should only include cases that present risk for the adverse event as utilizing an amplified denominator would provide a false reading of lower rates. A few commenters who supported the removal of these measures suggested that the measures could be redeveloped and submitted via QualityNet in the future. One commenter suggested that revising the data submission method in this way could capture data from all payers. One commenter noted that ASC–1, ASC–2, and ASC–3 specifically should include all patients in the denominator. A few commenters who opposed CMS' proposals to remove the measures stated that the measures could be redeveloped for all payers and could be reported via QualityNet in order to further reduce burden and ensure data is posted publicly for accountability and for quality improvement. A few commenters recommended that the measures could be included as part of

a composite measure that encompasses the various phases of care.

Response: The ASCQR Program is a quality reporting program for which ASCs must meet program requirements including the submission of quality measure data, else they are subject to a two percent reduction in their annual payment update. As a quality reporting program, the data collected is publicly reported in order to aide beneficiaries in choosing sites of care. Our regulations at 42 CFR part 416 detail the requirements that determine a facility's eligibility to participate as a Medicare supplier of ambulatory surgical services. We will continue to assess our measure set in light of stakeholder concerns and within the framework of our Meaningful Measures Initiative.

Currently, ASCs are only able to report adverse events for Medicare fee-for-service beneficiaries and that adverse events that have occurred to patients with other payers are not reflected in the currently reported data. As such, it is possible for an ASC to report zero adverse events via the ASCQR Program because no adverse events occurred to Medicare FFS beneficiaries within the reporting period. In addition, we thank the commenters for their suggestions regarding redeveloping the measure to capture all payers and to submit via QualityNet to reduce burden. We note that because the data for these measures are currently collected via Medicare FFS claims, as specified in the Specifications Manual,[165] we are unable to include data from other payers for which Medicare does not receive FFS claims.

We thank the commenters for the feedback and note that we are also concerned about some of the data submitted for these measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53641), we finalized our policy that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. At that time, we believed that 50 percent was a reasonable minimum threshold for the initial implementation years of the ASCQR Program, because ASCs were not yet familiar with how to report quality data under the ASCQR Program and because many ASCs are relatively small and may have needed more time to set up reporting systems. We stated in that final rule that we intended to propose to increase this percentage for subsequent years' payment determinations as ASCs become more familiar with reporting requirements for the ASCQR Program. We have assessed this reporting threshold annually and have found that over 78 percent of reporting ASCs report data for at least 90 percent of eligible claims. However, we believe that the current data submission method for these measures may impact the completeness and accuracy of the data due to the inability of ASCs to correct the QDC codes that are used to calculate these measures from Medicare FFS claims. Currently, a facility that identifies an erroneous or missing QDC code is unable to correct or add a QDC code if the claim has already been submitted to Medicare. We believe that revising the data submission method for the measures, such as via QualityNet, would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data. Further, we will conduct additional empirical analyses to identify any other potential issues with the data submitted for these measures. We refer readers to section XIV.B.6. of this final rule with comment period, where we discuss public comments received about the potential future validation of ASCQR Program measures.

We are committed to work with stakeholders to ensure the ASCQR Program measure set does not place an inappropriate amount of burden on facilities while addressing and providing information about these types of patient safety, adverse, rare events to patients and other consumers. As such, while we will retain ASC–1, ASC–2, ASC–3, and ASC–4 in the program as discussed above, after considering public comments and reevaluating our concerns about data submission, we will also suspend their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the data submission method for the measures. In other words, starting with the CY 2021 payment determination, facilities would not be required to submit data for these four measures as part of ASCQR Program requirements although the measures would remain in the ASCQR Program measure set. As we develop future revisions for the data collected for these measures, we will take into consideration other data submission methods that may allow for the reporting of adverse events across payers and will consider commenters' feedback toward the future updates to the measures.

Comment: A few commenters noted that it would be beneficial to also have these measures included in the Hospital OQR Program in order to provide patients with more meaningful data to compare sites of service.

Response: We thank the commenters for their feedback. We will take this into consideration for the future.

Comment: One commenter stated that the NQF endorsement of these measures was removed because they were allowed to lapse by the measure steward, not because they failed the endorsement maintenance process, and noted that the ASCQR Program did not provide this as a rationale for removing the measures. The commenter noted that all of these measures have ongoing support from the ASC community.

Response: NQF endorsement, or lack thereof, does not automatically qualify or disqualify a measure for removal from the ASCQR Program. We thank the commenter for its comment as ASC stakeholder feedback is important, and we will weigh the benefits of support of the ASC community in our consideration of our proposals to ensuring that the ASCQR Program has a robust and responsive measure set.

- Proposal To Remove ASC–1: Patient Burn

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497 through 74498) where we adopted ASC–1: Patient Burn beginning with the CY 2014 payment determination (NQF #0263). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–1 measure meets our measure removal Factor 1. These analyses are captured in the table below.

[165] Ambulatory Surgical Center Quality Reporting Specifications Manual, v7.0a. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772475754.*

ASC-1: Patient Burn Topped-Out Analysis

Encounters	Number of ASCs	75th Percentile	90th Percentile	Truncated COV
Q1-Q4 2013	4,768	100.00	100.00	0.023
Q1-Q4 2014	4,794	100.00	100.00	0.015
Q1-Q4 2015	4,783	100.00	100.00	0.011
Q1-Q4 2016	4,788	100.00	100.00	0.010
Q1-Q4 2017	4,814	100.00	100.00	0.008

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles, and the truncated coefficient of variation has been below 0.10 since 2013. In the proposed rule, we also noted that NQF endorsement of this measure (NQF #0263) was removed on May 24, 2016.[166]

Comment: One commenter specifically opposed the removal of ASC–1, noting that it measures rare, isolated events and that it is valuable to monitor for consumers as a burn measure.

Response: We thank the commenter for its feedback. While the measure is topped-out, we acknowledge that it is still valuable. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74497), we adopted this measure for ASCs because they serve surgical patients who may face the risk of burns during ambulatory surgical procedures and because we agree monitoring patient burns is valuable to patients and other stakeholders. Further, we have reviewed numerous studies demonstrating the high impact of monitoring patient burns due to the large number of surgeries performed in the outpatient setting,[167] because patient burns are serious reportable events in healthcare,[168] and because of patient burns are preventable.[169] [170] We note that we are not finalizing our proposal to remove ASC–1 as discussed in the section above.

- Proposal To Remove ASC–2: Patient Fall

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498) where we adopted ASC–2: Patient Fall beginning with the CY 2014 payment determination. This NQF-endorsed (NQF #0266), claims-based measure assesses the percentage of ASC admissions experiencing a fall in the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–2 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC-2: Patient Fall Topped-Out Analysis

Encounters	Number of ASCs	75th Percentile	90th Percentile	Truncated COV
Q1-Q4 2013	4,769	100.00	100.00	0.011
Q1-Q4 2014	4,793	100.00	100.00	0.007
Q1-Q4 2015	4,783	100.00	100.00	0.006
Q1-Q4 2016	4,787	100.00	100.00	0.003
Q1-Q4 2017	4,815	100.00	100.00	0.001

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013.

Comment: One commenter specifically opposed the removal of ASC–2, noting that ASC–2 measures rare, isolated events and that it is valuable to monitor for consumers as a patient fall measure.

Response: We thank the commenter for its feedback. While the measure is topped-out, we acknowledge that it is still valuable. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498), we adopted this measure for ASCs because falls, particularly in the elderly, can cause injury and loss of functional status, because the use of anxiolytics, sedatives, and anesthetic agents may put patients undergoing outpatient surgery at increased risk for falls, and because falls in healthcare settings can be prevented through the assessment of risk, care planning, and patient monitoring. Further, we have reviewed numerous studies demonstrating the high impact of monitoring patient burns due to the large number of surgeries performed in the outpatient setting,[171] because patient falls are serious reportable events in healthcare,[172] and because of patient falls are preventable.[173] Because

[166] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0263*.

[167] U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. *http://www.cms.gov/*.

[168] National Quality Forum. Serious Reportable Events in Healthcare 2006 Update. Washington, DC: NQF, 2007.

[169] ECRI Institute. New clinical guide to surgical fire prevention. Health Devices 2009 Oct;38(10):314–32.

[170] National Fire Protection Association (NFPA). NFPA 99: Standard for health care facilities. Quincy (MA): NFPA; 2005.

[171] U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. *http://www.cms.gov/*.

[172] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007.

[173] Boushon B, Nielsen G, Quigley P, Rutherford P, Taylor J, Shannon D. Transforming Care at the Bedside How-to Guide: Reducing Patient Injuries from Falls. Cambridge, MA: Institute for Healthcare Improvement; 2008.

of these concerns, we agree that monitoring patient falls is valuable to patients and other stakeholders. We note that we are not finalizing our proposal to remove ASC–2 as discussed in the previous section.

• Proposal To Remove ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499) where we adopted ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant beginning with the CY 2014 payment determination (NQF #0267). This claims-based outcome measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–3 measure meets our measure removal Factor 1. These analyses are captured in the table below.

ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant Topped-Out Analysis

Encounters	Number of ASCs	75th Percentile	90th Percentile	Truncated COV
Q1-Q4 2013	4,769	100.00	100.00	0.000
Q1-Q4 2014	4,793	100.00	100.00	0.000
Q1-Q4 2015	4,781	100.00	100.00	0.000
Q1-Q4 2016	4,787	100.00	100.00	0.000
Q1-Q4 2017	4,815	100.00	100.00	0.000

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. In the proposed rule, we also noted that NQF endorsement of this measure (NQF #0267) was removed on May 24, 2016.[174]

Comment: One commenter specifically opposed the removal of ASC–3, noting that although wrong site surgery is infrequent, it is an egregious error. The commenter was concerned that removing the measure would imply that it is no longer important to providers and also noted their belief that because ASCs tend to have more rapid patient turnover that may make them prone to ''never events'' such as wrong site surgeries.

Response: We thank the commenter for its feedback. While the measure is topped-out, we acknowledge that it is still valuable. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74498 through 74499), we adopted this measure for ASCs because surgeries and procedures performed on the wrong site/side, and wrong patient can result in significant impact on patients, including complications, serious disability or death. We also stated that while the prevalence of such serious errors may be rare, such events are considered serious reportable events. Further, we have reviewed numerous studies demonstrating the high impact of monitoring wrong site, wrong side, wrong patient, wrong procedure, wrong implant procedures and surgeries due to the large number of surgeries performed in the outpatient setting,[175] because these types of errors are serious reportable events in healthcare,[176] and because of these errors are preventable.[177] [178] Because of this, we agree that it is important to monitor this measure in ASCs, which perform a large volume of outpatient surgeries every year. We note that we are not finalizing our proposal to remove ASC–3 as discussed in the previous section.

• Proposal To Remove ASC–4: All-Cause Hospital Transfer/Admission

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499) where we adopted ASC–4: All-Cause Hospital Transfer/Admission beginning with the CY 2014 payment determination (NQF #0265). This claims-based outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

Based on our analysis of ASCQR Program measure data for CYs 2013 to 2017 encounters, the ASC–4 measure meets our measure removal Factor 1. These analyses are captured in the table below.

[174] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0267*.

[175] U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. *http://www.cms.gov/*.

[176] National Quality Forum. Serious Reportable Events in Healthcare—2006 Update: A Consensus Report. March 2007.

[177] American College of Obstetricians and Gynecologists. ACOG committee opinion #464: patient safety in the surgical environment. Obstet Gynecol. 2010;116(3):786–790.

[178] Joint Commission. Ambulatory Health Care: 2019 National Patient Safety Goals available at *https://www.jointcommission.org/ahc_2017_npsgs/*.

ASC-4: All Cause Hospital Transfer/Admission Topped-Out Analysis

Encounters	Number of ASCs	75th Percentile	90th Percentile	Truncated COV
Q1-Q4 2013	4,768	100.00	100.00	0.059
Q1-Q4 2014	4,793	100.00	100.00	0.050
Q1-Q4 2015	4,781	100.00	100.00	0.041
Q1-Q4 2016	4,787	100.00	100.00	0.040
Q1-Q4 2017	4,814	100.00	100.00	0.037

As displayed in the analysis above, there is no distinguishable difference in ASC performance between the 75th and 90th percentiles and the truncated coefficient of variation has been below 0.10 since 2013. In the proposed rule, we also noted that NQF endorsement of this measure (NQF #0265) was removed on February 4, 2016.[179]

Comment: One commenter specifically supported the inclusion of ASC–4 in the ASCQR Program, noting that it believed that the issues surrounding transfers to hospitals, although infrequent, are significant. The commenter noted that it believed that ASCs can only function safely if there is a hospital available to care for patients with unanticipated problems, noting that there can be an unclear and competitive relationship between the ASC and the hospital.

Response: While the measure is topped-out, we acknowledge that it is still valuable. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74499), we adopted this measure for ASCs because the transfer or admission of a surgical patient from an outpatient setting to an acute care setting can be an indication of a complication, serious medical error, or other unplanned negative patient outcome. We also stated that while acute intervention may be necessary in these circumstances, a high rate of such incidents may indicate suboptimal practices or patient selection criteria. Further, we have reviewed numerous studies demonstrating the high impact of monitoring patient transfers and admissions due to the large number of surgeries performed in the outpatient setting,[180] and because facilities can take steps to prevent and reduce these types of events.[181] [182] [183] On this basis, we agree that the issue of patient transfers to hospitals within the ASC setting are significant adverse events to beneficiaries and ASC stakeholders, even if infrequent.

Currently, 42 CFR 416.41(b)(3)(i) and (ii) requires ASCs to have a written transfer agreement with a hospital that meets certain Medicare requirements or ensure all physicians performing surgery in the ASC have admitting privileges in a hospital that meets certain Medicare requirements. A written transfer agreement and physician admitting privileges are intended to ensure there is a relationship between the ASC and local hospital that would serve the patient in the event of a medical emergency. We note that changes to these requirements were proposed in the Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction proposed rule (83 FR 47686) due to the difficulty of obtaining these agreements.

Over the past 5 years, we have heard from the largest ASC trade association and multiple ASCs that we need to address the widespread issue of the growing number of hospitals that are declining to work with ASCs (either by declining to sign a transfer agreement or by declining to allow admitting privileges to the hospital by physicians who work in ASCs) due to competition between hospital outpatient surgery departments and ASCs. We have continually worked with the ASCs and hospitals directly to resolve this requirement issue. However, we are aware that several facilities have not been able to reach a positive outcome.

On September 20, 2018, we issued a proposed rule in the **Federal Register** titled ''Medicare and Medicaid Programs: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction'' (83 FR 47686 through 47762). In that proposed rule (83 FR 47693 through 47694), we discussed proposals regarding ASC transfer agreements and admitting privileges. We noted that we have seen no evidence of negative patient outcomes due to a lack of such transfer agreements and admitting privileges, and research reports published by the ASC Quality Collaborative indicate the national hospital transfer rate from an ASC to a hospital for care is about 1.25 per 1,000 ASC admissions (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/index.html*). As we also noted in that proposed rule, ASCs are already required to have personnel trained and available for emergency response when there is a patient in the ASC, and the ASC is expected to provide initial stabilizing treatment until the patient is transferred. Finally, we noted that the current requirement dates back to 1982, when ASCs were a newly emerging medical care option and there was reasonable concern as to needed emergency care being available. As we noted above, we are not finalizing our proposal to remove ASC–4 as discussed in the section above.

Comment: One commenter was concerned that ASC–4 only includes data for Medicare patients and the potential for this to skew the data and misrepresent the facility's transfer rate, and recommended that CMS collect data for all cases regardless of payer type. The commenter was also concerned that by only reporting Medicare data for the measure, that it may create a disincentive for facilities to transfer a Medicare patient because it would raise their transfer rate.

Another commenter recommended that CMS expand ASC–4 to include patients who visit a hospital for an inpatient admission or emergency department visit in the days following their ASC procedure.

[179] National Quality Forum. Available at: *http://www.qualityforum.org/QPS/0265*.

[180] U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. *http://www.cms.gov/*.

[181] Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. J Clin Anesth. 2002 Aug; 14(5):349–53.

[182] Fortier J, Chung F, Su J. Unanticipated admission after ambulatory surgery—a prospective study. Can J Anaesth. 1998 Jul;45(7):612–9.

[183] Junger A, Klasen J, Benson M, Sciuk G, Hartmann B, Sticher J, Hempelmann G. Factors determining length of stay of surgical day-case patients. Eur J Anaesthesiol. 2001 May;18(5):314–21.

Response: We do not believe that the ASC–4 measure, as specified in the ASCQR Program Specifications Manual,[184] would create a disincentive for facilities to transfer a Medicare patient to a hospital because both the denominator, and the numerator as noted by the commenter, is comprised of all Medicare FFS beneficiaries that have been admitted to the ASC. We also note, that because ASC–4 is a claims-based measure, it is only able to assess transfer rates for Medicare FFS beneficiaries for which claims are received by CMS. We agree that measuring hospital visits after ASC procedures may be a valuable metric to Medicare beneficiaries and the public due to concerns about patient harm or complications. As such, we have already incorporated multiple measures assessing this area by adopting ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 66970), ASC–17: Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (82 FR 59454), and ASC–18: Hospital Visits After Urology Ambulatory Surgical Center Procedures (82 FR 59463) into the ASCQR Program measure set. We will continue to evaluate the ASCQR Program measure set to ensure it is robust and responsive to beneficiary needs and thank the commenter for the feedback. We note that we are not finalizing our proposal to remove ASC–4 as discussed in the previous section.

(b) Measure Removals Under Removal Factor 8: ASC–9, ASC–10, and ASC–11

In the proposed rule, we proposed to remove three measures (ASC–9, ASC–10, and ASC–11) under proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program, for the CY 2021 payment determination and subsequent years. In the proposed rule, we noted that if proposed measure removal Factor 8 is not finalized, removal of these measures would also not be finalized.

The proposals are discussed in more detail below. We note that in crafting our proposals, we considered removing these measures beginning with the CY 2020 payment determination but opted to delay removal until the CY 2021 payment determination to be sensitive to facilities' planning and operational procedures given that data collection for these measures begins during CY 2018 for the CY 2020 payment determination.

• Proposal To Remove ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) where we adopted ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the ''[p]ercentage of patients aged 50 years and older receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least ten (10) years for repeat colonoscopy documented in their colonoscopy report.'' (78 FR 75127). This measure aims to assess whether average risk patients with normal colonoscopies receive a recommendation to receive a repeat colonoscopy in an interval that is less than the recommended amount of ten (10) years.

In the proposed rule, we proposed to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years under our measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We adopted ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75127 through 75128) noting that performing colonoscopy too frequently increases patients' exposure to procedural harm. However, we noted concern in the proposed rule that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several current and historic clinical data quarters and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. We noted in the proposed rule that removing ASC–9 would reduce the burden and cost to facilities associated with collection of information and reviewing their data and performance associated with the measure.

However, we also acknowledged that we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities, especially when taking into consideration the availability of other CMS quality measures that are relevant in the clinical condition and highly correlated in performance across measures. In the proposed rule we noted another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) which measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within seven (7) days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970). Furthermore, in the proposed rule we noted our belief that the potential benefits of keeping ASC–9 in the program are mitigated by the existence of the same measure (Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients)[185] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we noted that the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will

[184] Version 7.0a of the ASCQR Program Specifications Manual is available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776140694.*

[185] QPP Measure Selection: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. Retrieved from: *https://qpp.cms.gov/mips/quality-measures.*

have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[186] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of the proposed rule and this final rule with comment period. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and those that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discussed in section XIV.B.3.b. of the proposed rule, where we proposed to adopt measure removal Factor 8, we noted that beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in another CMS program, we noted in the proposed rule that the burdens and costs associated with this measure outweigh the limited benefit to beneficiaries. As a result, we proposed to remove ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and for subsequent years. We note that the Hospital OQR Program proposed to remove a similar measure, OP–29: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients in section XIII.B.4.b. of the proposed rule.

Comment: Several commenters opposed CMS' proposal to remove ASC–9 from the ASCQR Program. A few commenters expressed concern that physicians may not follow the recommended guidelines for colonoscopy screenings and noted that there is a potential for patient harm from unnecessary colonoscopy screenings that pose significant costs. One commenter suggested that solely retaining the measure in MIPS is insufficient because the measure is voluntary in that program. A few commenters stated that ASC–9 and ASC–12 assess distinct and different aspects of colonoscopies, because ASC–12 focuses on coordination and does not evaluate the interval between colonoscopies or the appropriate use of care. One commenter noted that ASC–9 and ASC–12 fall into different Meaningful Measures categories, Preventable Healthcare Harm and Admissions and Readmissions, respectively. These commenters recommended retaining ASC–9 to achieve a holistic approach to measuring the quality of care in this clinical area. One commenter noted that ASC–9 is not overly burdensome to collect and report. Some commenters disagreed with CMS' assessment that the costs of the measure outweigh the benefit.

Response: Although MIPS-eligible clinicians may voluntarily select measures from a list of options, we believe that MIPS reporting would provide some meaningful data in this clinical area. While we proposed to remove this measure because we believed the costs associated with a measure outweigh the benefit of its continued use in the program, after reviewing public comments, we reevaluated our data and analysis. We acknowledge that adherence to clinical guidelines for colonoscopy screening intervals is an important issue due to studies that document inappropriate use.[187] [188] [189] One study showed high rates of inappropriate colonoscopies performed in older adult populations: 10 percent in adults aged 70–75; 39 percent in adults aged 76–85; and 25 percent in adults aged ≥86.[190] We believe that ASC–9 is a critical measure for the ASCQR Program because there is demonstrated substantial overuse of surveillance colonoscopies among low-risk patients,[191] with research showing that colonoscopies are often recommended at shorter intervals than are advised by guidelines among patients with normal colonoscopy results.[192] We believe it is especially important to assess this topic due to the high-volume of these procedures that occur in the outpatient setting.

Furthermore, while ASC–9 and ASC–12 assess the topic of colonoscopies generally, we acknowledge that they assess distinct clinical areas. ASC–12 tracks adverse patient outcomes that result in unplanned hospital visits; ASC–9 provides information about colonoscopies occurring at inappropriate intervals that may contribute to increased costs to beneficiaries and to CMS, a priority of our Meaningful Measures Initiative. While ASC–12 provides vital data about patient outcomes after colonoscopies, ASC–9 focuses on adherence to guideline recommendations for screening colonoscopy follow-up intervals, as noted by NQF's evaluation report.[193] Upon reviewing the measure set as a whole, we now believe that ASC–9 assesses a distinct clinical area not addressed by ASC–12 and as a result, there may be a measurement gap if both ASC–9 and ASC–10 are removed. Further, although we noted that ASC–9 requires the burden of chart-abstraction to report, we believe it is significantly less burdensome than ASC–10 due to the significant burden of obtaining patient histories required for that measure. We also appreciate commenters' feedback that ASC–9 is not overly burdensome to report. Because this measure tracks the number of beneficiaries who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their

[186] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

[187] Sheffield et al. 2013. Potentially Inappropriate Screening Colonoscopy in Medicare Patients: Variation by Provider and Geographic Region. JAMA Intern Med.

[188] Schoen R. E., Pinsky P. F., Weissfeld J. L., et al. Utilization of surveillance colonoscopy in community practice. Gastroenterology. 2010;138(1):73–81. doi: 10.1053/j.gastro.2009.09.062.

[189] Krist, AH, Jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.

[190] Sheffield et al. 2013. Potentially Inappropriate Screening Colonoscopy in Medicare Patients: Variation by Provider and Geographic Region. JAMA Intern Med.

[191] Schoen R. E., Pinsky P. F., Weissfeld J. L., et al. Utilization of surveillance colonoscopy in community practice. Gastroenterology. 2010;138(1):73–81. doi: 10.1053/j.gastro.2009.09.062.

[192] Krist, AH, Jones, RM, Woolf, SH et al. Timing of Repeat Colonoscopy: Disparity Between Guidelines and Endoscopists' Recommendation. American Journal of Preventive Medicine. 2007.

[193] NQF #0658 Endoscopy/Polyp Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients, Date Submitted: Jul 09, 2012 National Quality Form, Stage 1 Concept Submission and Evaluation Worksheet 1.0.

colonoscopy report, we believe it provides important information to beneficiaries on the avoidance of inappropriate endoscopies/colonoscopies. ASC–9 evaluates overutilization that can lead to the overuse of resources and unnecessary risks to beneficiaries from possible procedural complications and harms.

In section I.A.2. of the proposed rule and this final rule with comment period, we describe our Meaningful Measures Initiative that is intended to reduce costs and minimize burden. We believe that although removing this chart-abstracted measure from the ASCQR Program would reduce program complexity, retaining it provides pertinent information about colonoscopies occurring at inappropriate intervals that may contribute to increased costs to beneficiaries and to CMS, a priority of our Meaningful Measures Initiative.

Despite the costs and burdens of chart-abstraction or the presence of other measures assessing a similar clinical topic, after considering incoming comments and reevaluating our data, we now believe ASC–9 is a more critical measure for the ASCQR Program than we initially perceived in the proposed rule. Accordingly, upon further review of the benefits of the measure, we no longer believe that the costs associated with this measure outweigh the benefit of its continued use in the program. Therefore, we are not finalizing our proposal to remove this measure. This measure will remain in the program under our measure retention policies, unless we take future action under our measure removal policies.

Comment: A few commenters stated that CMS should retain ASC–9 in order to promote program alignment across outpatient settings and allow for comparisons between facility types.

Response: We have considered program alignment by adding and removing measures in tandem for the ASCQR and Hospital OQR Programs so that measures may be compared across facility types, such as ASC–9/OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients. As noted above, we adopted ASC–9 into the ASCQR Program because we believe it is important for ASCs to be active partners in avoiding inappropriate use and ensuring that beneficiaries at their facilities are referred for follow-up care at appropriate intervals in alignment with current guidelines. As stated above, we are not finalizing our proposal to remove ASC–9. We are similarly retaining the corresponding measure (OP–29) in the Hospital OQR Program in section XIII.B.4.b. of this final rule with comment period.

Comment: One commenter did not support CMS' proposal to remove ASC–9 because it is included in the CMS Core Quality Measures Collaborative (CQMC) Gastroenterology Core Set and is widely used in the private sector.

Response: The CMS CQMC identifies core sets of quality measures that payers have committed to using for reporting as soon as feasible.[194] The guiding principles used by the Collaborative in developing the core measure sets are that they be meaningful to patients, consumers, and physicians, while reducing variability in measure selection, collection burden, and cost. The goal is to establish broadly agreed upon core measure sets that could be harmonized across both commercial and government payers.[195] We agree that the inclusion of ASC–9 in the CMS CQMC Gastroenterology Core Set speaks to its clinical value. However, although we are retaining ASC–9 for the reasons discussed in this section, we note that the inclusion of measures in the CQMC Core Sets does not necessitate retention in the ASCQR Program.

Comment: One commenter recommended that CMS retain ASC–9 and explore how to automate tracking of the information to reduce the resource-intensive use of chart-abstracted data. Another commenter recommended that CMS retain the measure because it could be useful for validation, as it is a chart-abstracted measure.

Response: We thank the commenter for the suggestion regarding automated data submission and will take this into consideration for the future. As discussed in section I.A.2 of this final rule with comment period, our Meaningful Measures Initiative prioritizes burden reduction in our quality reporting programs, and we will continue to evaluate the ASCQR Program measure set through this framework. We continually seek opportunities to reduce the reporting burden of our programs, but note that collecting data for ASC–9 still currently requires chart-abstraction.

In section XIV.B.6. of this final rule with comment period, we discuss public comments we received on the possible future validation of ASCQR Program measures and will include this comment in our consideration of that request for information. As discussed in detail above, after consideration of the public comments we received, we are not finalizing our proposal to remove ASC–9.

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program. Several commenters specifically supported CMS' proposal to remove ASC–9 from the ASCQR Program, noting that it was developed and tested as a provider-level measure and they did not believe it is appropriate for the ASC setting. A few commenters further stated that this measure is already being reported through the MIPS (formerly PQRS) and that MIPS is the appropriate program because ASC–9 is a provider-level measure.

Response: We thank the commenters for their support. As noted in our proposal, this same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about avoiding inappropriate use. In addition, as noted when we adopted this measure (78 FR 75125), it was specified for the ASC setting and field tested at the ASC facility setting level by the measure steward. Further, we believe it is important for ASCs to be active partners in avoiding inappropriate use and ensuring that patients at their facilities are referred for follow-up care at appropriate intervals in alignment with current guidelines. In addition, after considering the public comments we received and upon further review of the benefits of the measure, we no longer believe that the costs associated with this measure outweigh the benefit of its continued use in the program as this measure assesses a unique and clinically important topic area not covered otherwise addressed by the ASCQR Program measure set.

After consideration of the comments we received, we are not finalizing our proposal to remove ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients from the ASCQR Program beginning with the CY 2021 payment determination and for subsequent years. This measure will remain in the program under our measure retention policies, unless we take future action under our measure removal policies. We note that we are also not finalizing our proposal to remove OP–29 under the Hospital OQR Program, and we refer readers to section XIII.B.4.b. of this final

[194] Core Measures. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.*

[195] Ibid.

rule with comment period for more information.

• Removal of ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients With a History of Adenomatous Polyps—Avoidance of Inappropriate Use

We refer readers to CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) where we adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use (NQF #0659) beginning with the CY 2016 payment determination. This chart-abstracted process measure assesses the percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior colonic polyp in previous colonoscopy findings, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report.

In the proposed rule, we proposed to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use beginning with the CY 2021 payment determination and for subsequent years under our proposed measure removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.

We adopted ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75128) noting that colonoscopy screening for high risk patients is recommended based on risk factors, and one such factor is a history of adenomatous polyps. The frequency of colonoscopy screening varies depending on the size and amount of polyps found, with the general recommendation of a 3-year follow-up. We stated that this measure is appropriate for the measurement of quality of care furnished by ASCs, because colonoscopy screening is commonly performed in these settings (78 FR 75128). However, we now believe that the costs of this measure outweigh the benefit of its continued use in the program.

Chart-abstraction requires facilities to select a sample population, access historical records from several clinical data quarters past, and interpret that patient data. This process is typically more time and resource-consuming than for other measure types. In addition to submission of manually chart-abstracted data, we take all burden and costs into account when evaluating a measure. Removing ASC–10 would reduce the burden and cost to facilities associated with collection of information and reporting on their performance associated with the measure.

However, we do not believe the use of chart-abstracted measure data alone is sufficient justification for removal of a measure under proposed measure removal Factor 8. The costs of collection and submission of chart-abstracted measure data is burdensome for facilities especially when taking into consideration the availability of other CMS quality measures. Another colonoscopy-related measure required in the ASCQR Program, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539) measures all-cause, unplanned hospital visits (admissions, observation stays, and emergency department visits) within seven (7) days of an outpatient colonoscopy procedure (79 FR 66970). This claims-based outcome measure does not require chart-abstraction, and similarly contributes data on quality of care related to colonoscopy procedures, although the measure does not specifically track processes such as follow-up intervals. When we adopted ASC–12, we believed this measure would reduce adverse patient outcomes associated with preparation for colonoscopy, the procedure itself, and follow-up care by capturing and making more visible to facilities and patients all unplanned hospital visits following the procedure (79 FR 66970). Furthermore, the potential benefits of keeping ASC–10 in the ASCQR Program are mitigated by the existence of the same measure (Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use) [196] for gastroenterologists in the Merit-Based Incentive Payment System (MIPS) for the 2019 performance period in the QPP (82 FR 30292). Thus, we believe the issue of preventing harm to patients from colonoscopy procedures that are performed too frequently is adequately addressed through MIPS in the QPP, because we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS. Although MIPS-eligible clinicians may voluntarily select measures from a list of options, ASC providers that are MIPS-eligible will have the opportunity to continue collecting information for the measure without being penalized if they determine there is value for various quality improvement efforts.[197] The availability of this measure in another CMS program demonstrates CMS' continued commitment to this measure area.

Furthermore, we seek to align our quality reporting work with the Patients Over Paperwork and the Meaningful Measures Initiatives described in section I.A.2. of the proposed rule and this final rule with comment period. The purpose of this effort is to hold providers accountable for only the measures that are most important to patients and clinicians and that are focused on patient outcomes in particular, because outcome measures evaluate the actual results of care. As described in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden, and we believe that removing this chart-abstracted measure from the ASCQR Program would reduce program complexity. In addition, as we discussed in section XIV.B.3.b. of the proposed rule, where we proposed to adopt measure removal Factor 8, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Therefore, due to the combination of factors of the costs of collecting data for this chart-abstracted measure, the preference for an outcomes measure in the ASCQR Program that provides valuable data for the same procedure, and the existence of the same measure in the MIPS program, we believe that the burdens and costs associated with manual chart abstraction outweigh the limited benefit to beneficiaries of receiving this information. As a result, we proposed to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use from the ASCQR Program beginning with the CY 2021 payment determination and for subsequent years. We note that we proposed to remove a similar measure from the Hospital OQR Program in section XIII.B.4.b. of the proposed rule.

[196] QPP Measure Selection: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. Retrieved from: *https://qpp.cms.gov/mips/quality-measures*.

[197] CMS finalized that services furnished by an eligible clinician that are payable under the ASC, HHA, Hospice, or HOPD methodology will not be subject to the MIPS payments adjustments, but eligible clinicians payable under those methodologies may have the option to still voluntarily report on applicable measures and the data reported will not be used to determine future eligibility (82 FR 53586).

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program. Several commenters specifically supported CMS' proposal to remove ASC–10 from the ASCQR Program because the costs outweigh the benefits of retaining it in the ASCQR Program. One commenter noted that unless the reporting facility was the site of the patient's previous procedure, the reporting facility would not have the data necessary from their medical records and would need to obtain it from other providers, including the date of the procedure, and the number types, and locations of any polyps found. One commenter recommended that CMS remove ASC–10 beginning with the CY 2020 payment determination, so that facilities may shift resources dedicated to operationalizing the measure sooner.

Response: We thank the commenters for their support. In addition to the burden of chart-abstraction, we acknowledge the unique burden of ASC–10, which requires that facilities conduct extensive patient histories and contact other facilities in order to obtain documentation of a history of adenomatous polyps.[198] Thus, the costs and burdens are higher for this measure than for the other coloscopy measure considered for removal, ASC–9, which requires less information from patients and does not require historical documentation.

Comment: Several commenters noted that ASC–10 was developed and tested as a provider-level measure and they do not believe it is appropriate for the ASC setting. One commenter stated that this measure is already being reported through the MIPS (formerly PQRS) and that MIPS is the appropriate program because ASC–10 is a provider-level measure. Another commenter stated that duplicate reporting in CMS' quality reporting programs has caused unnecessary provider burden without adding new information to the pool of quality data available to the public.

Response: We adopted ASC–10 into the ASCQR Program because we believe it is important for ASCs to be active partners in avoiding inappropriate use and ensuring that beneficiaries at their ASCs are referred for follow-up care at appropriate intervals in alignment with current guidelines. In addition, as noted when we adopted this measure (78 FR 75125), it was specified for the ASC setting and field tested at the ASC setting level by the measure steward. As noted in our proposal, this same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about avoiding inappropriate use.

As discussed above, we are retaining ASC–9 in order to retain a measure assessing inappropriate use of endoscopies/colonoscopies in the ASCQR Program. After reconsideration, we believe there may be a measurement gap if both ASC–9 and ASC–10 are removed and because of the unique burden associated with ASC–10, we are finalizing our removal of this measure but retaining ASC–9. A primary goal of our Meaningful Measures Initiative is to reduce provider burden through the deduplication of measures across quality reporting programs. Thus, due in part to the duplication of this measure through MIPS in the QPP and the additional burden to ASCs of obtaining patient records, we believe ASC–10 is the more appropriate measure to be removed from the ASCQR Program measure set. Removing ASC–10 while retaining ASC–9 best enables us to assess this important clinical area while ensuring that the costs of measure do not outweigh the benefits.

Comment: A few commenters opposed CMS' proposal to remove ASC–10 from the ASCQR Program. One commenter noted that ASC–10 is a cost measure and helps avoid inappropriate use or missed opportunities to screen patients that could result in significant harm to beneficiaries. One commenter expressed concern that physicians may not follow the recommended guidelines for colonoscopy screenings and noted that there is a potential for patient harm from unnecessary colonoscopy screenings that poses significant costs.

Response: We agree that adherence to clinical guidelines for colonoscopy screening intervals is an important issue. Measuring the inappropriate use of colonoscopy screenings is critical to preventing the waste of resources and potential patient harm. In part for this reason, we are retaining ASC–9 in the ASCQR Program measure set and will continue to require reporting on appropriate follow-up intervals for normal risk patients. We believe that retaining ASC–9 in the ASCQR Program enables us to address concerns regarding patient harm from unnecessary colonoscopy screenings.

Further, due to the unique documentation burden specifically for ASC–10, we believe it adds undue burden to ASCs, particularly small ASCs and those that do not have EHRs and is more burdensome than ASC–9. After review of public comments we received, we reevaluated our data and our measure set as a whole. To balance the clinical value of measures with the costs, we believe it is appropriate to retain ASC–9 while finalizing our proposal to remove ASC–10.

Comment: One commenter did not support CMS' proposal to remove ASC–10 because it is included in the CMS CQMC Gastroenterology Core Set and is widely used in the private sector.

Response: The CMS CQMC Gastroenterology Core Set is a set of measures identified as being meaningful to patients, consumers, and physicians, while reducing variability in measure selection, collection burden, and cost and is intended for use by payers who are part of the CQMC.[199] Because of this, we believe beneficiaries will continue to receive this data to help them make health care decisions. We agree that this measure is valuable to many stakeholders and support its continued reporting through other quality reporting programs and in the private sector. However, due to the measure's requirement to obtain historical patient records, we believe that this measure adds undue burden to ASCs, particularly small ASCs and those that do not have EHRs. In addition, we note that the inclusion of measures in the CQMC Core Sets does not necessitate retention in the ASCQR Program.

Comment: A few commenters stated that ASC–10 and ASC–12 assess distinct different aspects of colonoscopies, because ASC–12 focuses on care coordination and does not evaluate the interval between colonoscopies or the appropriate use of care. One commenter notes that ASC–10 and ASC–12 fall into different Meaningful Measures categories, Preventable Healthcare Harm and Admissions and Readmissions, respectively.

Response: We thank the commenters for their feedback. We agree that ASC–10 and ASC–12 assess distinct clinical areas, but do assess the topic of colonoscopies generally. While ASC–12 tracks adverse patient outcomes that result in unplanned hospital visits, ASC–10 provides information about colonoscopies occurring at inappropriate intervals for beneficiaries that may contribute to increased costs to beneficiaries and to CMS, a priority of

[198] ASC–10 Measure Information Form. Available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228776607946.*

[199] Core Measures. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.*

our Meaningful Measures Initiative. However, we believe ASC–10 should be removed because it is uniquely burdensome, as described above, and because our retention of ASC–9 allows us to continue to address inappropriate use of colonoscopy screening.

After consideration of the public comments we received, we are finalizing our proposal to remove ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use from the ASCQR Program beginning with the CY 2021 payment determination and for subsequent years, as proposed. We refer readers to section XIII.B.4.b. of this final rule with comment period where we are removing a similar measure from the Hospital OQR Program.

• Proposal To Remove ASC–11: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129) where we adopted ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) beginning with the CY 2016 payment determination. This measure assesses the rate of patients 18 years and older (with a diagnosis of uncomplicated cataract) in a sample who had improvement in visual function achieved within 90 days following cataract surgery based on completing both a preoperative and postoperative visual function survey.

Since the adoption of this measure, we came to believe that it can be operationally difficult for ASCs to collect and report the measure (79 FR 66984). Specifically, we were concerned that the results of the survey used to assess the preoperative and post-operative visual function of the patient may not be shared across clinicians and facilities, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery (79 FR 66984). We were also concerned about the surveys used to assess visual function; the measure allows for the use of any validated survey and results may be inconsistent should clinicians use different surveys (79 FR 66984). Therefore, on December 31, 2013, we issued guidance stating that we would delay data collection for ASC–11 for three (3) months (data collection would commence with April 1, 2014 encounters) for the CY 2016 payment determination (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772879036*). We issued additional guidance on April 2, 2014, stating that we would further delay the implementation of ASC–11 for an additional 9 months, until January 1, 2015 for the CY 2016 payment determination, due to continued concerns (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228773811586*). As a result of these concerns, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years.

In the proposed rule, we proposed to remove ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the ASCQR Program beginning with the CY 2021 payment determination under proposed measure removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We originally adopted ASC–11 because we believe ASCs should be a partner in care with physicians and other clinicians using their facility and that this measure would provide an opportunity to do so (79 FR 66984). However, in light of the history of complications and upon reviewing this measure within our Meaningful Measures framework, we have concluded that it is overly burdensome for ASCs to report this measure due to the difficulty of tracking care that occurs outside of the ASC setting.

In order to report on this measure to CMS, a facility would need to obtain the visual function assessment results from the appropriate ophthalmologist and ensure that the assessment utilized is validated for the population for which it is being used. If the assessment is not able to be used or is not available, the ASC would then need to administer the survey directly and ensure that the same visual function assessment tool is utilized preoperatively and postoperatively. There is no simple, preexisting means for information sharing between ophthalmologists and ASCs, so an ASC would need to obtain assessment results from each individual patient's ophthalmologist both preoperatively and postoperatively. The high administrative costs of the technical tracking of this information presents an undue cost, and also burden associated with submission and reporting of ASC–11 to CMS, especially for small ASCs with limited staffing capacity.

Furthermore, this measure currently provides limited benefits. Since making the measure voluntary, only 118 ASCs have reported this measure to CMS, compared to approximately 5,121 total ASCs for all other measures, resulting in only 2.3 percent of ASC reporting.[200] Consequently, we have been unable to uniformly offer pertinent information to beneficiaries on how the measure assesses ASC performance. This reinforces comments made in the CY 2015 OPPS/ASC final rule with comment period, in which commenters expressed concern that the voluntary reporting of this measure would result in incomplete data that may be confusing to beneficiaries and other consumers (79 FR 66984). As we state in section I.A.2. of the proposed rule and this final rule with comment period, we strive to ensure that beneficiaries are empowered to make decisions about their healthcare using information from data-driven insights. Because of the lack of sufficient data, this measure may be difficult for beneficiaries to interpret or use to aid in their choice of where to obtain care; thus, the benefits of this measure are limited.

Therefore, we stated that we believed the high technical and administrative costs of this measure outweigh the limited benefit associated with its continued use in the ASCQR Program. As discussed in section I.A.2. of the proposed rule and this final rule with comment period, our Meaningful Measures Initiative is intended to reduce costs and minimize burden. We believed that removing this measure from the ASCQR Program will reduce program burden, costs, and complexity. As a result, we proposed to remove ASC–11 beginning with the CY 2021 payment determination and for subsequent years. We also proposed to remove a similar measure under the Hospital OQR Program in section XIII.B.4.b. of the proposed rule.

Comment: A few commenters opposed all of CMS' proposals to remove measures, including ASC–11.

Response: In response to the commenters who requested that measures, including ASC–11, be retained, we reevaluated our measures and data. We found that a core group of ASCs (between 107 and 137 for each year between the CY 2017 through CY 2019 payment determinations) report on this voluntary measure. Although only a subset of ASCs voluntarily report this measure, we believe it is considered

[200] ASCQR Compare Data. Available at: *https://data.medicare.gov/Hospital-Compare/Ambulatory-Surgical-Quality-Measures-Facility/4jcv-atw7/data.*

very meaningful by those ASCs that do report because these facilities do so consistently (38 ASCs submitted consistently for the CY 2017 through CY 2019 payment determinations). Because this subset of ASCs has consistently reported this measure we are able to make the data publicly available year after year—in this case, for the CYs 2017, 2018, and 2019 payment determinations.[201] We think providing data on this voluntary measure is still helpful for the public because it shows how an ASC performs over time and in comparison to other ASCs even if compared to a small group of ASCs.

Furthermore, this is the only measure in the ASCQR Program measure set that deals with cataract surgery, which is commonly performed in the ASC setting. If it is removed, the program will have a gap in coverage for this clinical area. As a result, we now believe that meaningful information can be provided to consumers regarding those facilities. In addition, when this measure was made voluntary in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984) commenters stated that the measure would promote and improve care coordination among providers.

Furthermore, we have reassessed our evaluation that the costs of this measure outweigh the benefits. Due to the voluntary nature of the measure, we believe that it is inherently not more burdensome than valuable. Because ASCs are not required to submit data, those that do not have the capacity to report, do not have to, thus creating no extra burden. Those that do report, do so voluntarily and have continued to report over the years—specifically since the CY 2015 reporting period—despite any burdens. Because of this, we believe the measure is meaningful to the core group of facilities that do consistently report.

Therefore, we are not finalizing our proposal to remove ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the ASCQR Program beginning with the CY 2021 payment determination and for subsequent years. This measure will remain in the program under our measure retention policies, unless we take future action under our measure removal policies.

Comment: Many commenters supported all of CMS' proposals to remove measures from the ASCQR Program. Several commenters specifically supported CMS' proposal to remove ASC–11 and agreed with CMS' assessment that the costs of this measure outweigh the benefit of retaining it in the ASCQR Program. One commenter remarked that the lack of consistent data and the difficulty of abstracting the data from ophthalmologists' medical records posed a significant and unacceptable data collection burden for the measure. One commenter recommended that CMS remove ASC–11 beginning with the CY 2020 payment determination, so that ASCs may shift resources dedicated to operationalizing the measure sooner.

Response: We thank the commenters for their support. As noted in the proposed rule, we agree that data collection for this measure may be difficult, and as a result in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to allow voluntary data collection and reporting of this measure beginning with the CY 2017 payment determination and for subsequent years. However, we believe ASCs should be a partner in care with physicians and other clinicians using their facility and this measure is an opportunity for hospitals to demonstrate this capability if they choose to report it. In addition, as noted above, we no longer believe that the costs of this measure outweigh the benefits, as the measure is meaningful. Further, while data collection for this measure can be difficult, those facilities that choose to report do so year after year despite any burdens.

Comment: Several commenters noted that the measure was endorsed by the NQF as a physician-level, rather than facility-level, measure and that therefore it was never intended for the ASC setting. A few commenters noted that the measure is included in the MIPS (former PQRS Program) as a clinician-level measure and is therefore redundant in the ASC setting. One commenter noted that as a voluntary measure, ASC–11 did not have widespread participation and therefore had minimal impact on the care of patients.

Response: As we noted when we adopted this measure (78 FR 75125), it was specified for the ASC setting and field tested at the ASC facility setting level by the measure steward. We believe it is important for ASCs to be active partners in ensuring improvement in patients' visual function following cataract surgeries. As commenters correctly noted, this same measure is available through MIPS in the QPP and, although MIPS-eligible clinicians may voluntarily select measures from a list of options, and we expect a portion of MIPS-eligible clinicians reporting on the measure nationwide to provide meaningful data to CMS about this important outcome for beneficiaries. We agree that as a voluntary measure that only a subset of ASCs participating in the ASCQR Program reported on the measure, but note it is a meaningful measure to beneficiaries given that our analyses show that a consistent group of facilities report data on this measure. So, while data is not available for all facilities, the data that is available is meaningful.

After consideration of the public comments we received, we are not finalizing our proposal to remove ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery from the ASCQR Program beginning with the CY 2021 payment determination and for subsequent years. We also note that we are retaining a similar measure under the Hospital OQR Program, OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery in section XIII.B.4.b.(2)(a) of this final rule with comment period.

4. ASCQR Program Quality Measures Adopted in Previous Rulemaking

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59470) for the previously finalized ASCQR Program measure set for the CY 2020 payment determination and subsequent years.

5. Summary of ASCQR Program Quality Measure Sets Finalized for the CY 2020, CY 2021, and CY 2022 Payment Determinations

In the CY 2019 OPPS/ASC proposed rule, we did not propose any new measures for the ASCQR Program. The tables below summarize the ASCQR Program measure sets as finalized in this final rule with comment period for the CY 2020, 2021, and 2022 payment determinations (including previously adopted measures and measures finalized for removal in this final rule with comment period). We note that the tables reflect that we are finalizing our proposal to change the reporting period for one previously adopted measure, ASC–12, and we refer readers to section

[201] *Hospital Compare ASCQR: https://www.medicare.gov/hospitalcompare/asc-ascqr.html.*

XIV.D.4.b. of this final rule with comment period for details.

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Finalized ASCQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
ASC-1	0263†	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff**
ASC-15b	None	OAS CAHPS – Communication About Procedure**
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery**
ASC-15d	None	OAS CAHPS – Overall Rating of Facility**
ASC-15e	None	OAS CAHPS – Recommendation of Facility**

† NQF endorsement was removed.

* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

**Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

Finalized ASCQR Program Measure Set for the CY 2021 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
ASC-1	0263†	Patient Burn*
ASC-2	0266	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***
ASC-15e	None	OAS CAHPS – Recommendation of Facility***

† NQF endorsement was removed.

* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in section XIV.B.3.c.(2)(a) of this final rule with comment period.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

Finalized ASCQR Program Measure Set for the CY 2022 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
ASC-1	0263†	Patient Burn*
ASC-2	0266	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***
ASC-15e	None	OAS CAHPS – Recommendation of Facility***
ASC-17	None	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	None	Hospital Visits after Urology Ambulatory Surgical Center Procedures

† NQF endorsement was removed.

* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in section XIV.B.3.c.(2)(a) of this final rule with comment period.

** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

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6. ASCQR Program Measures and Topics for Future Consideration: Possible Future Validation of ASCQR Program Measures

In the CY 2019 OPPS/ASC proposed rule (83 FR 37204), we requested public comment on the possible future validation of ASCQR Program measures. There is currently no validation of ASCQR measure data, and we believe ASCs may benefit from the opportunity to better understand their data and examine potential discrepancies. We believe the ASCQR Program may similarly benefit from the opportunity to produce a more reliable estimate of whether an ASC's submitted data have been abstracted correctly and provide more statistically reliable estimates of the quality of care delivered in each selected ASC as well as at the national level. We believe the Hospital OQR Program validation policy could be a good model for the ASCQR Program and are requesting comment on the validation methodology and identifying one measure with which to start.

The Hospital OQR Program requires validation of its chart-abstracted measures. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965) for a discussion of finalized policies regarding Hospital OQR Program validation requirements, which are also codified at 42 CFR 419.46(e). Under the Hospital OQR Program, CMS selects a random sample of 450 hospitals and an additional 50 hospitals based on the following criteria: (1) The hospital failing of the validation requirement that applies to the previous year's payment determination; or (2) the hospital having an outlier value for a measure based on data that it submits. An ''outlier value'' is defined as a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score. Then, CMS or its contractor provides written requests to the randomly selected hospitals by requesting

supporting medical record documentation used for purposes of data submission under the program. The hospital must submit the supporting medical record documentation within 45 days of the date written in the request. A hospital meets the validation requirement with respect to a calendar year if it achieves at least a 75 percent reliability score, as determined by CMS.

Specifically, for the ASCQR Program, we are interested in the validation of chart-abstracted measures. We believe it would be beneficial to start with validation of just one measure, such as ASC–13: Normothermia Outcome, prior to expanding to more measures. ASC–13: Normothermia Outcome was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79798 through 79801) and assesses the percentage of patients having surgical procedures under general or neuraxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in the post-anesthesia care unit. We also considered starting with ASC–14: Unplanned Anterior Vitrectomy instead, which was finalized in the 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803) and assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy. However, we believe ASC–13 would be the most feasible measure for validation because it assesses surgical cases and would have a larger population of cases from which to sample. ASC–14, which assesses rare, unplanned events that are less common, would have a smaller population of cases from which to sample.

Therefore, we invited public comment on the possible future validation of ASCQR Program measures. We specifically request comment on whether Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program, the possible ASC sample size, sampling methodology, number of cases to sample, validation score methodology, and reduced annual payment updates for facilities that do not pass validation requirements. We also requested comment on possibly starting with only one measure, specifically ASC–13, before expanding to more measures.

Comment: A few commenters supported the possible validation of ASCQR Program data through a program similar to Hospital OQR Program validation. These commenters noted that this would further align the programs and provide accountability for the accuracy of reporting.

Response: We thank the commenters for their support.

Comment: One commenter opposed validation of ASCQR Program measures, citing the cost and burden to providers and CMS. This commenter recommended that CMS instead invest in ways to receive timelier and meaningful data related to patient quality and safety. One commenter was concerned about the burden to ASCs of the validation process due to the low level of EHR adoption among ASCs as compared to hospital outpatient departments, noting that the majority of ASCs may need to submit paper records.

Response: We thank the commenters for their feedback regarding additional program impact of validation for the ASCQR Program. As noted above, we will take facility burden into consideration regarding the selection of measures for the potential future validation of ASCQR Program measures.

Comment: One commenter was concerned that setting the sample size of ASCs at or around 500, comparable to Hospital OQR Program, would represent a significantly larger percentage of ASCs reporting chart-abstracted measures under the ASCQR Program than under the Hospital OQR Program. The commenter recommended that a smaller number of ASCs be selected for validation, perhaps based on the percentage of HOPDs selected for validation under the Hospital OQR Program. Another commenter stated that a similar random sample to the Hospital OQR Program (450 ASCs) could be utilized, as well as an additional number of ASC's with outlier values. One commenter was concerned about ASCs that fail to record adverse events and recommended that CMS develop additional sampling criteria based on selecting ASCs that have a ''good score'' outlier rate.

Response: We thank the commenters for their suggestions regarding sampling for any validation scheme considered for the ASCQR Program and will take these into consideration as we move forward.

Comment: A few commenters supported beginning validation with only one measure, with one noting it would allow participants time to understand the program and its implications for payment. Some commenters supported using ASC–13 as an initial measure for validation within the ASCQR Program, with a few commenters noting it is an important and prescient measure for outpatient settings.

Response: We thank the commenters for their feedback supporting validation for the ASCQR Program and the possible use of ASC–13 for this purpose. We agree that it is most feasible to begin potential future validation of measures in the ASCQR Program with a single measure.

Comment: A few commenters expressed concern about using ASC–13 as an initial measure for validation within the ASCQR Program. One commenter noted their belief that ASC–13 is not indicative of care at an ASC. Another commenter expressed concern that ASC–13 is reported as a sample with an aggregated-web based metric and that patient-level information is not submitted by ASCs. One commenter was concerned about incongruent definitions of normothermia among quality reporting programs and recommended that if discrepancies are found during the validation process that anesthesia professionals be held harmless. Another commenter stated that ASC–14 would be a better initial measure for validation, noting that cases requiring general or neuraxial anesthesia are less common than cataract surgery and would likely have a smaller population of cases from which to sample.

Response: We thank the commenters for their feedback and will further examine ASC–13 and ASC–14 case volumes, appropriate methods of validation of aggregated web-based metrics, and normothermia definitions among quality reporting programs.

Comment: A commenter noted that not all ASCs report data for ASC–13 and ASC–14 due to not performing cases involving general/neuraxial anesthesia of 60 minutes or more in duration (ASC–13) and/or cataract surgery (ASC–14), and noted their concern that ASCs that do report these measure would bear more burden and be required to meet a higher threshold for retaining their APU. The commenter recommended only selecting measures for validation that are applicable to all ASCs. Another commenter recommended that all measures should be validated, with the prioritization for ASC–1, ASC–2, and ASC–3 in order to study closely the occurrence of adverse events. A commenter recommended that the ASCQR Program implement validation only when more manually abstracted measures are added to the program, noting that implementing a validation process for a small number of measures is burdensome and may yield only limited value to CMS.

Response: We thank the commenters for their feedback regarding alternate measures to consider for validation under the ASCQR Program. We agree that the percentage of ASCs actually reporting on a measure is an important

consideration in choosing measures for validation. We will investigate the feasibility of validating ASC–1, ASC–2, and ASC–3. We will further assess the potential burden impact of the potential future validation of any ASCQR Program measures. We note that one of the goals of our Meaningful Measures Initiative is to move the ASCQR Program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures.

Comment: One commenter was concerned that ASCs submit aggregated web-based data on an annual basis and that sampling is allowed for the submission of ASC–13 data without patient identifying information. The commenter recommended that CMS consider selection bias if ASC–13 data is validated.

Response: We thank the commenter for its feedback and agree that there is a potential for selection bias if the aggregated web-based data for ASC–13 is validated. We will take this potential for selection bias into consideration as we craft future policy.

We thank the commenters for their views and will take them into consideration as we determine future policy regarding validation in the ASCQR Program.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74513 through 74514), where we finalized our proposal to follow the same process for updating the ASCQR Program measures that we adopted for the Hospital OQR Program measures, including the subregulatory process for updating adopted measures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68496 through 68497), the CY 2014 OPPS/ASC final rule (78 FR 75131), and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66981), we provided additional clarification regarding the ASCQR Program policy in the context of the previously finalized Hospital OQR Program policy, including the processes for addressing nonsubstantive and substantive changes to adopted measures. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531), we provided clarification regarding our decision to not display the technical specifications for the ASCQR Program on the CMS website, but stated that we will continue to display the technical specifications for the ASCQR Program on the QualityNet website. In addition, our policies regarding the maintenance of technical specifications for the ASCQR Program are codified at 42 CFR 416.325. In the CY 2019 OPPS/ASC proposed rule (83 FR 37204), we did not propose any changes to our policies regarding the maintenance of technical specifications for the ASCQR Program.

8. Public Reporting of ASCQR Program Data

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74514 through 74515), we finalized a policy to make data that an ASC submitted for the ASCQR Program publicly available on a CMS website after providing an ASC an opportunity to review the data to be made public. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70531 through 70533), we finalized our policy to publicly display data by the National Provider Identifier (NPI) when the data are submitted by the NPI and to publicly display data by the CCN when the data are submitted by the CCN. In addition, we codified our policies regarding the public reporting of ASCQR Program data at 42 CFR 416.315 (80 FR 70533). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79819 through 79820), we formalized our current public display practices regarding timing of public display and the preview period by finalizing our proposals to: Publicly display data on the *Hospital Compare* website, or other CMS website as soon as practicable after measure data have been submitted to CMS; to generally provide ASCs with approximately 30 days to review their data before publicly reporting the data; and to announce the timeframes for each preview period starting with the CY 2018 payment determination on a CMS website and/or on our applicable listservs. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59470), we discussed specific public reporting policies associated with two measures beginning with the CY 2022 payment determination: ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, and ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37204 through 37205), we did not propose any changes to our public reporting policies.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account, and the associated timelines, for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding maintenance of a QualityNet account and security administrator for the ASCQR Program at 42 CFR 416.310(c)(1)(i). In the CY 2018 OPPS/ASC final rule (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes to the 42 CFR 416.310(c)(1)(i). In the CY 2019 OPPS/ASC proposed rule (83 FR 37205), we did not propose any changes to these policies.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 and 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. In the CY 2019 OPPS/ASC proposed rule (83 FR 37205), we did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37205), we did not propose any changes to these requirements. However, in the proposed rule we noted that in section XIV.B.3.c. of the proposed rule, beginning with the CY 2021 payment determination and for subsequent years, we proposed to

remove all four claims-based measures currently using QDCs:

- ASC–1: Patient Burn;
- ASC–2: Patient Fall;
- ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC–4: Hospital Transfer/Admission.

We are not finalizing our proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4, as described further in section XIV.B.3.c.(2)(a) of this final rule with comment period, and are instead retaining the measures in the ASCQR Program and suspending their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the measures. However, we did not propose any changes to our requirements regarding data processing and collection periods for these types of measures. These requirements will apply to any future claims-based measures using QDCs adopted in the program.

2. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. In the CY 2019 OPPS/ASC proposed rule (83 FR 37205), we did not propose any changes to these policies.

3. Requirements for Data Submitted via an Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein) and 42 CFR 416.310(c) for our previously finalized policies for data submitted via an online data submission tool. For more information on data submission using QualityNet, we refer readers to: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2✖QnetTier2&cid=1228773314768*.

a. Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (that is, the CDC NHSN website). We codified our existing policies regarding the data collection time periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2).

Currently, we only have one measure (ASC–8: Influenza Vaccination Coverage among Healthcare Personnel) that is submitted via a non-CMS online data submission tool. In the proposed rule, we noted that we proposed this measure for removal for the CY 2020 payment determination and subsequent years in section XIV.B.3.c. of the proposed rule. Because we are finalizing the removal of ASC–8 as proposed, no measures submitted via a non-CMS online data submission tool will remain in the ASCQR Program beginning with the CY 2020 payment determination. However, we did not propose any changes to our non-CMS online data submission tool reporting requirements; these requirements would apply to any future non-CMS online data submission tool measures adopted in the program.

b. Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the QualityNet website as our CMS online data submission tool: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetHomepage&cid=1120143435383*. We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes to the 42 CFR 416.310(c)(1)(i).

In the CY 2019 OPPS/ASC proposed rule (83 FR 37205 through 37206), we did not propose any changes to this policy. However, in the proposed rule we noted that in sections XIV.B.3.c. of the proposed rule, we proposed to remove three measures collected via a CMS online data submission tool—ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients, ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use, and ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery [202] beginning with the CY 2021 payment determination. Because we are finalizing ASC–10 for removal as proposed and are not finalizing our proposals to remove ASC–9 and ASC–11 in the ASCQR Program measure set (these measures will remain in the program), the following measures will require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- ASC–9: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- ASC–11: Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery
- ASC–13: Normothermia Outcome
- ASC–14: Unplanned Anterior Vitrectomy

4. Requirements for Non-QDC Based, Claims-Based Measure Data

In the CY 2019 OPPS/ASC proposed rule (83 FR 37206 through 37207), we did not propose any changes to our requirements for non-QDC based, claims-based measures. However, in the proposed rule we proposed to change the reporting period for the previously adopted measure, ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. This proposal is discussed in more detail further below.

a. General

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536) for our previously adopted policies regarding data processing and reporting periods for claims-based measures for the CY 2018 payment determination and subsequent years. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70536), we codified these policies at 42 CFR 416.310(b). In the proposed rule, we did not propose any changes to these policies. We note that the non-QDC, claims-based measures in the program are as follows:

- CY 2020 payment determination and subsequent years: ASC 12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (79 FR 66970 through 66978)

[202] We note that the ASC–11 measure is voluntarily collected effective beginning with the CY 2017 payment determination, as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

- CY 2022 payment determination and subsequent years:
  - ASC–17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)
  - ASC–18: Hospital Visits after Urology Ambulatory Surgical Center Procedures (82 FR 59455 through 59470)

b. Extension of the Reporting Period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66970 through 66978), we finalized the adoption of ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy into the ASCQR Program for the CY 2018 payment determination and subsequent years, with public display to begin on or after December 1, 2017. This measure is calculated with data obtained from paid Medicare FFS claims (79 FR 66978). For this reason, facilities are not required to submit any additional information. In that final rule with comment period, we also finalized the reporting period for measure calculation as claims data from two calendar years prior to the payment determination year. Specifically, for the CY 2018 payment determination, we stated we would use paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate measure results (79 FR 66985). We finalized a 1-year reporting period as it adequately balanced competing interests of measure reliability and timeliness for payment determination purposes, and explained that we would continue to assess this during the dry run (79 FR 66973).

We noted we would complete a dry run of the measure in 2015 using three or four years of data, and, from the results of this dry run, we would review the appropriate volume cutoff for facilities to ensure statistical reliability in reporting the measure score (79 FR 66974). Our analyses of the 2015 dry run using data from July 2011 through June 2014 showed that a reporting period of one year had moderate to high reliability for measure calculation. Specifically, using data from July 2013 through June 2014, we calculated facility-level reliability estimates as the ratio of true variance to observed variance.[203] Consistent with the original measure specifications as described in the 2014 technical report,[204] this calculation was performed combining the measure results for HOPDs and ASCs. We found that for a facility with median case size, the reliability estimate was high (over 0.90), but the minimum reliability estimate for facilities with 30 cases (the minimum case size chosen for public reporting) was only moderate (that is, between 0.40 and 0.60).[205]

However, after the 2015 dry run, CMS calculated the HOPD and ASC scores separately to compare similar types of facilities to each other. During subsequent analysis of the 1-year reporting period of July 2013 through June 2014, we confirmed that a 1-year reporting period with separate calculations for HOPDs and ASCs was sufficient, but did result in lower reliability and decreased precision, compared to results calculated with longer reporting periods (two or three years). Based on analyses conducted using data from July 2013 through June 2014 (1-year reporting period) and 2017 measure specifications,[206] we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs. Using a 2-year reporting period (data from July 2012–June 2014), we found that median facility-level reliability was 0.81 for ASCs and 0.67 for HOPDs. When the reporting period was extended to three years (using data from July 2011 through June 2014), we found that median facility-level reliability was higher for both ASCs and HOPDs: 0.87 for ASCs and 0.75 for HOPDs. These results indicate that a larger portion of the included facilities have scores measured with higher reliability when three years of data are used rather than one year of data.

Using three years of data, compared to just one year, is estimated to increase the number of ASCs with eligible cases for ASC–12 by 10 percent, adding approximately 235 additional ASCs to the measure calculation. ASCs reporting the measure would increase their sample sizes and, in turn, increase the precision and reliability of their measure scores. Thus, we believe extending the reporting period to three years from one year for purposes of increasing reliability would be beneficial for providing better information to beneficiaries regarding the quality of care associated with low-risk outpatient colonoscopy procedures. In crafting our proposal, we considered extending the reporting period to two years beginning with the CY 2020 payment determinations and subsequent years, but decided on proposing three years instead, because a higher level of reliability is achieved with a 3-year reporting period compared to two years.

Therefore, in the CY 2019 OPPS/ASC proposed rule (83 FR 37206 through 37207), we proposed to change the reporting period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination (which would use claims data from January 1, 2016 through December 31, 2018) and for subsequent years. Under this proposal, the annual reporting requirements for ASCs would not change because this is a claims-based measure. However, with a 3-year reporting period, the most current year of data would be supplemented by the addition of two prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus two prior years of data (CYs 2016 and 2017). In the proposed rule, we noted that since implementation of this measure began with the CY 2018 payment determination, we have already used paid Medicare FFS claims from January 1, 2016 to December 31, 2016 to calculate the measure scores, which have been previously previewed by ASCs and publicly displayed. In crafting our proposal, we also considered timeliness related to payment determinations and public display. Because we would utilize data already collected to supplement current data, our proposal to use three years of data would not disrupt payment determinations or public display. We refer readers to the table below for example reporting periods and public display dates corresponding to the CY 2020, CY 2021, and CY 2022 payment determinations:

[203] Snijders TA, Bosker RJ. *Multilevel Analysis: An introduction to basic and advanced multilevel modeling.* SAGE Publications. 2000. London.

[204] Additional methodology details and information obtained from public comments for measure development are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

[205] Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* 1977;33(1):159–174.

[206] Current and past measure specifications are available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775214597.*

	CY 2020 Payment Determination	CY 2021 Payment Determination	CY 2022 Payment Determination
Public display	January 2020	January 2021	January 2022
Reporting period	January 1, 2016 – December 31, 2018	January 1, 2017 – December 31, 2019	January 1, 2018 – December 31, 2020

We refer readers to section XIII.D.4.b. of the proposed rule, where we discussed a similar proposal under the Hospital OQR Program.

Comment: Several commenters supported the proposed extension of the reporting period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. A few commenters supported a 3-year reporting period, noting that the reliability of measure data intended for public reporting and accountability is important and urged CMS to seek stakeholder feedback on developing a methodology and release a methodology report for public review and comment.

Response: We thank the commenters for their support for extending the reporting period for ASC–12. Regarding the request to release a methodology report, we publish an annual update and measures specifications report, which is a description of the measure updates and measure results from reevaluation and includes detailed measure specifications.[207] This report describes the measure methodology for a given reporting period. CMS encourages stakeholders to submit comments on the measure's methodology via the Outpatient and ASC Question and Answer tool, *https://cms-ocsq.custhelp.com/*.

Comment: One commenter stated that in order to make the measure data as reliable as possible, CMS should increase the minimum case volume threshold from less than thirty cases to less than one hundred cases.

Response: While it is true that a higher minimum case count would result in a higher minimum reliability, we must balance the goal of adequate reliability with the goal of providing measure performance information on as many facilities as possible. The minimum case count of 30 was set during the dry run of the measure and resulted in a minimum reliability estimate that was ''moderate'' for those facilities meeting the requirement. While the measure now calculates score for ASCs and OPDs separately, increasing the number years used for the measure should increase reliability for facilities meeting this minimum case count. We must balance the goal of adequate reliability with the goal of providing timely measure information that can inform quality improvement efforts. A 3-year reporting period improves the reliability of the measure and increases the number of facilities that meet the minimum case count.

Comment: A few commenters supported a 2-year reporting period, stating that priority interest should be giving beneficiaries critical information they can use today and two years of data typically yields the best mix of reliability and predicting performance today.

Response: We chose to propose a 3-year reporting period for the colonoscopy measure because using three years of data would increase the number of facilities meeting minimum case count requirements and increase the overall reliability of each facility measure score by increasing sample sizes. We balance the goal of adequate reliability with the goal of providing timely measure information that can inform quality improvement efforts. A 3-year reporting period substantially improves the reliability of the measure, as described above. Using a 1-year reporting period, we found that the median facility-level reliability was 0.74 for ASCs and 0.51 for HOPDs, and for a 2-year reporting period 0.81 for ASCs and 0.67 for HOPDS. However, the median facility-level reliability was highest for both ASCs and HOPDs using a 3-year reporting period: 0.87 for ASCs and 0.75 for HOPDs. In addition, we note that using a 3-year reporting period does not affect the timeliness of our ability to report on this measure, as the data being used has already been collected. Specifically, we note that the most current year of data would be supplemented by the addition of two prior years. For example, for the CY 2020 payment determination, we would use a reporting period of CY 2018 data plus two prior years of data (CYs 2016 and 2017).

Comment: Several commenters provided general feedback on the measure. A few noted that the data reported for the two measures (ASC–12 and OP–32) reflects fundamental claim and billing policy differences—such as the CMS three-day payment window—between the two settings (ASCs and HOPDs) that preclude valid comparisons, and the two measures should be clearly distinguished. A few commenters noted that the all-cause ED visit outcome is too broad and is not giving any specific information about the quality of care given at an endoscopy center, and that the measure does not help the consumer make distinctions among ASCs.

Response: We thank commenters for their feedback on the measure. The commenter is correct that there are differences between the ASC and HOPD colonoscopy measures (ASC–12 and OP–32) that specifically relate to billing differences between the two settings. For example, for outpatient (HOPD) colonoscopies that occur in the three calendar days preceding the date of a beneficiary's inpatient admission, the facility claim is bundled with the inpatient claim, and therefore would not be identified using only outpatient facility claims. Therefore, for OP–32, cases subject to the 3-day payment window are identified with a matching algorithm that uses inpatient and physician (Medicare Part B) claims to attribute the colonoscopy procedure to the appropriate outpatient facility (HOPD).[208] [209] We also calculate the measure scores separately for ASCs and HOPDs; HOPDs are only compared to other HOPDs, and ASCs to other ASCs, therefore the difference in methodology does not affect the overall evaluation of ASCs or HOPDs within each measure's calculation. Furthermore, we note that ASC–12 and OP–32 performance data are presented separately on *Hospital Compare*. In the future, we intend to update publicly available resource materials to clarify that ASC–12 and OP–32 are calculated separately using

[207] Measure Methodology. Colonoscopy measure. Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775197506*.

[208] Ranasinghe I, Parzynski C, Searfoss S, et al. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy: A Quality Measure for Profiling Facility Performance Using Claims Data. 2014; *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775197506*. Accessed October 22, 2018.

[209] Version 7.0a of the ASCQR Program Specifications Manual is available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2Page%2FSpecsManualTemplate&cid=1228776140694*.

different benchmarks and should not be compared.

In addition, we measure all-cause hospital visits (including Emergency department visits) to encourage OPDs and ASCs to minimize all types of risks that may lead to hospital visits after a colonoscopy. Measuring only hospital visits that are narrow procedural complications of colonoscopy, such as gastrointestinal bleeding, would limit the measure's impact on quality improvement efforts and miss events such as dehydration, pain, dizziness, and urinary retention that are often related to the colonoscopy or the preparation for the colonoscopy and present to the ED. From the patient's perspective, these events reflect the quality of care for the full episode of care. Measuring all-cause patient outcomes encourages facilities and their clinicians minimizes the risk of a broad range of outcomes. We have structured the measure so that OPDs and ASCs that most effectively minimize patient risk of these outcomes will perform better.

While we employ a conservative approach to categorizing facility performance relative to the national rate, the distribution of measure scores for both ASC–12 and OP–32 demonstrate meaningful variation. This variation provides valuable information to facilities about their performance and the possibility for reducing complications following low risk colonoscopies. Using claims from January 1, 2016 through December 31, 2016, we characterize the degree of variability by calculating the median odds ratio (MOR). The median odds ratio represents the median increase in odds of a hospital visit if a procedure on a single patient was performed at a higher risk facility compared to a lower risk facility. Both median odds ratios indicate the impact of quality on the outcome rate is substantial at both ASCs and HOPDs.

- For HOPDs, a value of 1.23 indicates that a patient has a 23 percent increase in the odds of a hospital visit if the same procedure was performed at higher risk HOPD compared to a lower risk HOPD.
- For ASCs, a value of 1.19 indicates that a patient has a 19 percent increase in the odds of a hospital visit if the same procedure was performed at higher risk ASC compared to a lower risk ASC.

After consideration of the public comments we received, we are finalizing our proposal to change the reporting period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination and for subsequent years, as proposed. We refer readers to section XIII.D.4.b. of this final rule with comment period, where we are finalizing a similar policy under the Hospital OQR Program.

5. Requirements for Data Submission for ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified these policies at 42 CFR 416.310(e). However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), we delayed implementation of the ASC–15a–e: OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking, and we refer readers to that discussion for more details. In the CY 2019 OPPS/ASC proposed rule (83 FR 37207), we did not propose any changes to this policy.

6. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) Changed the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018; and (2) revised 42 CFR 416.310(d) of our regulations to reflect this change. We also clarified that we will strive to complete our review of each request within 90 days of receipt. In the CY 2019 OPPS/ASC proposed rule (83 FR 37207), we did not propose any changes to these policies.

7. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. In the CY 2019 OPPS/ASC proposed rule (83 FR 37207), we did not propose any changes to this policy.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to section XVI.D.1. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system equal the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2019, the ASC conversion factor we are finalizing is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted hospital market basket update factor. The MFP adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted hospital market basket update is the annual update for the ASC payment system for an interim 5-year period (CY 2019 through CY 2023). As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72062), if the CPI–U update factor is a negative number, the CPI–U update factor would be held to zero. In the CY 2019 OPPS/ASC proposed rule (83 FR 37207), consistent with past practice, in the event the percentage change in the hospital market basket for a year is negative, we proposed to hold the hospital market basket update factor for the ASC payment system to zero. Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs

2019 through 2023, we refer readers to section XII.G. of this final rule with comment period.

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in section XII.D.2.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS and when they are integral to covered ASC surgical procedures will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015, CY 2016, CY 2017, and CY 2018 OPPS/ASC final rules with comment period (79 FR 66981 through 66982; 80 FR 70537 through 70538; 81 FR 79825 through 79826; and 82 FR 59475 through 59476, respectively), we did not make any other changes to these policies. We did not propose any changes to these existing policies for CY 2019 in the CY 2019 OPPS/ASC proposed rule (83 FR 37207 through 37208).

We did not receive any public comments on our proposal that, in the event the percentage change in the hospital market basket for a year is negative, we would hold the hospital market basket update factor for the ASC payment system to zero. We also did not receive any public comments on our existing policies for all other applicable adjustments to the ASC national unadjusted payment rates discussed earlier. Therefore, we are finalizing our proposal without modification and continuing the existing policies for CY 2019.

XV. Comments Received in Response To Requests for Information (RFIs) Included in the CY 2019 OPPS/ASC Proposed Rule

In the CY 2019 OPPS/ASC proposed rule (83 FR 37208 through 37217), we included three requests for information (RFIs). We stated in the proposed rule that the RFIs were issued solely for information and planning purposes; none of the RFIs constituted a Request for Proposal (RFP), application, proposal abstract, or quotation. In addition, we stated that the RFIs did not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we stated that CMS was not seeking proposals through these RFIs and would not accept unsolicited proposals. Responders were advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs would be solely at the interested party's expense. In addition, we stated in the proposed rule that failing to respond to either RFI would not

preclude participation in any future procurement, if conducted. We also stated that it is the responsibility of the potential responders to monitor each RFI announcement for additional information pertaining to the request. We also noted that CMS would not respond to questions about the policy issues raised in these RFIs. In addition, we stated that CMS may or may not choose to contact individual responders, and that such communications would only serve to further clarify written responses. In the proposed rule, we stated that contractor support personnel may be used to review RFI responses. We also stated that responses to these RFIs were not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. We stated that information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis and that respondents should not include any information that might be considered proprietary or confidential. We stated that these RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. We also stated that all submissions become U.S. Government property and will not be returned. We posted the public comments that CMS received on the three RFIs as part of the posting of the public comments received on the CY 2019 OPPS/ASC proposed rule on the website at: *www.regulations.gov*.

A. Comments Received in Response To Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 OPPS/ASC proposed rule (83 FR 37209 through 37211), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received over 60 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Comments Received in Response To Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 OPPS/ASC proposed rule (83 FR 37211 and 37212), we included a Request for Information (RFI) related to improving beneficiary access to provider and supplier charge information as part of our price transparency initiatives. We received over 90 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

C. Comments Received in Response To Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

In the CY 2019 OPPS/ASC proposed rule (83 FR 37212 through 37217), we included a Request for Information (RFI) related to leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center Model. We received approximately 80 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

XVI. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Background

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38323 through 38411) for the measures and program policies we have adopted for the Hospital IQR Program through the FY 2020 payment determination and subsequent years. In addition to the proposed and finalized policies discussed in this section, we also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41609) for a full discussion of the Hospital IQR Program and its policies.

B. Update to the HCAHPS Survey Measure (NQF #0166) for the FY 2021 Payment Determination and Subsequent Years

1. Background of the HCAHPS Survey in the Hospital IQR Program

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37218), CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (NQF #0166) [210] (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital IQR Program (at the time called the Reporting Hospital Quality Data Annual Payment Update Program, or RHQDAPU) in the CY 2007 OPPS final rule with comment period (71 FR 68202 through 68204) beginning with the FY 2008 payment determination and for subsequent years. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FY 43882), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50222), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342) for details on previously-adopted HCAHPS Survey requirements.

The HCAHPS Survey (OMB control number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients 32 questions about their recent hospital stay. The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and 6 weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries.[211] Hospitals must survey patients throughout each month of the year.[212] The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, and Portuguese versions. The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS *Quality Assurance Guidelines,* which is available on the official HCAHPS website at: *http://www.hcahpsonline.org/en/quality-assurance/*. AHRQ carried out a rigorous scientific process to develop and test the HCAHPS Survey instrument. This process entailed multiple steps, including: a public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder

[210] The HCAHPS measure also includes the NQF-endorsed Care Transition Measure (CTM–3) (NQF #0228), which we added in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516). We added the Communication About Pain composite measure in the FY 2018 IPPS/LTCH PPS final rule (38328 through 38342), and stated that we would seek NQF endorsement for this measure.

[211] We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 to 38342, 38398) and to the official HCAHPS website at: *http://www.hcahpsonline.org* for details on HCAHPS requirements.

[212] Ibid.

input; a 3-State pilot test; small-scale field tests; and notice-and-comment rulemaking. In May 2005, the HCAHPS Survey was first endorsed by the NQF.[213]

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), out of an abundance of caution, in the face of a nationwide epidemic of opioid overprescription, we finalized a refinement to the HCAHPS Survey measure as used in the Hospital IQR Program by removing the previously adopted pain management questions and incorporating new Communication About Pain questions beginning with patients discharged in January 2018, for the FY 2020 payment determination and subsequent years.[214] These three survey questions within the HCAHPS Survey, collectively known as the Communication About Pain questions,[215] address how providers communicate with patients about pain. These questions are as follows: [216]

- HP1: ''During this hospital stay, did you have any pain?''

☐ Yes

☐ No → *If No, Go to Question* ____

- HP2: ''During this hospital stay, how often did hospital staff talk with you about how much pain you had?''

☐ Never

☐ Sometimes

☐ Usually

☐ Always

- HP3: ''During this hospital stay, how often did hospital staff talk with you about how to treat your pain?''

☐ Never

☐ Sometimes

☐ Usually

☐ Always

In addition, we finalized public reporting on the Communication About Pain questions, such that hospital performance data on those questions would be publicly reported on the *Hospital Compare* website beginning October 2020, using CY 2019 data. We also stated that we would provide performance results based on CY 2018 data on the Communication About Pain questions to hospitals in confidential preview reports, upon the availability of four quarters of data, as early as July 2019. We believed implementing the Communication About Pain questions as soon as feasible was necessary to address any perceived conflict between appropriate management of opioid use and patient satisfaction by relieving any potential pressure physicians may feel to overprescribe opioids (82 FR 38333).

2. Updates to the HCAHPS Survey: Removal of Communication About Pain Questions

As discussed in the CY 2019 OPPS/ASC proposed rule (83 FR 37218), since we finalized the Communication About Pain questions, we have received feedback that some stakeholders are concerned that, although the revised questions focus on communications with patients about their pain and treatment of that pain, rather than how well their pain was controlled, the questions still could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS Survey. In addition, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[217]

Other potential factors outside the control of CMS quality program requirements may contribute to the perception of a link between the Communication About Pain questions and opioid prescribing practices, including: misuse of the HCAHPS Survey (such as using it for outpatient emergency room care instead of inpatient care, or using it for determining individual physician performance); failure to recognize that the HCAHPS Survey excludes certain populations from the sampling frame (such as those with a primary substance use disorder diagnosis); and the addition of supplemental pain-related survey questions by the hospital that are not formally part of the HCAHPS Survey or otherwise required by CMS.

Because some hospitals have identified patient experience of care as a potential source of competitive advantage, we have heard from stakeholders that some hospitals may be disaggregating their raw HCAHPS Survey data to compare, assess, and incentivize individual physicians, nurses, and other hospital staff. Some hospitals also may be using the HCAHPS Survey to assess their emergency and outpatient departments. To be clear, the HCAHPS Survey was never designed or intended to be used in these ways.[218] In our HCAHPS Quality Assurance Guidelines,[219] which sets forth current survey administration protocols, we strongly discourage the unofficial use of HCAHPS scores for comparisons within hospitals, such as for comparisons of particular wards, floors, and individual staff hospital members. The standardization of HCAHPS Survey administration and data collection methodologies is also emphasized during the required introductory and annual update trainings for hospitals/survey vendors.

As we stated in the CY 2019 OPPS/ASC proposed rule, we continue to believe that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers. It is important to reiterate that the HCAHPS Survey does not specify any particular type of pain control method. The revised questions focus entirely on communication about pain with patients and do not refer to, recommend, or imply that any particular type of treatment is appropriate (82 FR 38333). In addition, appropriate pain management includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making, proper prescription practices, and alternative treatments for pain management.

Although we are not aware of any scientific studies that support an association between scores on the prior or current iterations of the Communication About Pain questions and opioid prescribing practices, out of an abundance of caution and to avoid any potential unintended consequences, in the CY 2019 OPPS/ASC proposed rule (83 FR 37218), we proposed to update the HCAHPS Survey by removing the Communication About Pain questions effective with January

[213] Available at: *http://www.qualityforum.org/Publications/2008/08/National_Voluntary_Consensus_Standards_for_Hospital_Care_2007__Performance_Measures.aspx.*

[214] In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862), the Hospital VBP Program removed the Pain Management dimension of the HCAHPS Survey in the Patient and Caregiver-Centered Experience of Care/Care Coordination domain of the Hospital VBP Program beginning with the FY 2018 program year. Under the Hospital VBP Program, payment adjustments are tied to hospitals' performance on the measures that are used to calculate each hospital's Total Performance Score.

[215] Available at: *http://hcahpsonline.org/en/survey-instruments/.*

[216] We note that in the CY 2019 OPPS/ASC proposed rule, we inadvertently omitted the ''If No, Go to Question ____'' phrase that accompanies the ''No'' response option for the first question. We have added the language above to reflect the full question.

[217] Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

[218] Tefera L, Lehrman WG, and Conway P. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association.* Available at: *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

[219] HCAHPS *Quality Assurance Guidelines* (v. 13.0), available at: *http://www.hcahpsonline.org/en/quality-assurance/.*

2022 discharges, for the FY 2024 payment determination and subsequent years. This proposal would reduce the overall length of the HCAHPS Survey from 32 to 29 questions, and the final four quarters of reported Communication About Pain data (comprising data from the first, second, third, and fourth quarters 2021) would be publicly reported on *Hospital Compare* in October 2022 and then subsequently discontinued. As stated above, in its final report, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended removal of the HCAHPS Pain Management Survey questions in order to ensure providers are not incentivized to offer opioids to raise their HCAHPS Survey score.[220]

In proposing removal of the Communication About Pain questions, we did not propose to change how performance scores are calculated for the remaining questions on the HCAHPS Survey. The Hospital IQR Program is a quality data reporting program; payments to hospitals will not be affected so long as hospitals timely submit data on required measures and meet all other program requirements. We stated in the proposed rule that we would continue to use the remaining 29 questions of the HCAHPS Survey to assess patients' experience of care, and would continue to publicly report hospital scores on those questions in order to ensure patients and consumers have access to these data while making decisions about their care. Patients and providers can continue to review data from responses to the remaining 29 questions of the HCAHPS Survey on the *Hospital Compare* website.

In crafting our proposal, we considered whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. For example, instead of public reporting starting in October 2020 as previously finalized, we could have proposed to delay public reporting of the Communication About Pain questions until October 2021. We stated we were interested in feedback on whether the Communication About Pain questions should be retained in both the HCAHPS Survey and the Hospital IQR Program but with a further delay in public reporting. Delay in public reporting would allow further time to engage a broad range of stakeholders and assess their feedback regarding use of the Communication About Pain questions in the HCAHPS Survey and the Hospital IQR Program and to assess the impact of the new Communication About Pain questions. However, we chose to propose to remove the Communication About Pain questions as discussed above instead, so providers would not perceive that there are incentives for prescribing opioids to increase HCAHPS Survey scores.

In crafting our proposal, we also considered proposing earlier removal of the Communication About Pain questions from the HCAHPS Survey effective as early as January 2020 discharges, for the FY 2022 payment determination and subsequent years. However, we stated that removing the questions effective with January 2020 discharges would not allow sufficient time to make necessary updates to the data collection tools, including the CMS data submission warehouse and associated reporting tools, as well as to update the HCAHPS Survey administration protocols and the survey tool itself. In addition, our proposal to make these updates effective later, with January 2022 discharges, would allow time to assess the potential impact of using the Communication About Pain questions while monitoring unintended consequences. It would also allow time for empirical testing for any potential effect the removal of the Communication About Pain questions might have on responses to the remaining non-pain related survey items.

We invited public comment on our proposal as discussed above and whether the questions should be removed from the HCAHPS Survey and Hospital IQR Program. We stated that we were particularly interested in receiving feedback on any potential implications on patient care related to removing these questions. We also expressed interest in receiving feedback from stakeholders on: (1) The importance of receiving feedback from patients related to communication about pain management and the importance of publicly reporting this information for use both by patients in healthcare decision-making and by hospitals in focusing their quality improvement efforts; (2) additional analyses demonstrating a relationship between the use of pain questions in patient surveys and prescribing behavior, including unpublished data, if available; (3) input from clinicians and other providers concerning whether it would be valuable for CMS to issue guidance suggesting that hospitals do not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to the HCAHPS Survey, as well as the potential implementation of a third party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care; (4) information from clinicians and other providers concerning instances of hospital administrators using results from the HCAHPS Survey to compare individual clinician performance directly to other clinicians at the same facility or institution and examples where, as a result, clinicians have felt pressured to prescribe opioids inappropriately (in terms of either quantity or appropriateness for particular patients); (5) suggestions for other measures that would capture facets of pain management and related patient education, for instance, collecting data about a hospital's pain management plan, and provide that information back to consumers; and (6) how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives.

Comment: A number of commenters responded to CMS' request for feedback regarding potential misuse of the HCAHPS Survey and its impact on provider decision-making. Commenters indicated the Communication About Pain questions in the HCAHPS Survey unduly influence providers' decision-making by encouraging providers to focus on improving patient satisfaction scores regarding pain management. One commenter indicated this influence is significant enough to compel providers to prescribe opioids to patients showing signs of drug-seeking behavior. Other commenters expressed concern that some hospitals use disaggregated survey results to assess individual clinician performance, with some hospitals tying these disaggregated survey results to individual compensation.

Response: We thank the commenters for their feedback. We also reiterate that the HCAHPS Survey was never intended to be used to assess the performance of individual clinicians or provider groups within a hospital. The HCAHPS Survey is designed to evaluate the performance of a hospital as a whole, not individuals or groups within the larger hospital setting;[221] therefore,

[220] Final Report, The President's Commission on Combating Drug Addiction and the Opioid Crisis, available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.*

[221] Tefera L, Lehrman WG, and Conway P. ''Measurement of the Patient Experience: Clarifying Facts, Myths, and Approaches.'' *Journal of the American Medical Association.* Available at: *http://jama.jamanetwork.com/article.aspx?articleid=2503222.*

its use for evaluating or incentivizing individual providers or groups within the hospital is contrary to the survey's design and policy aim.

During annual survey vendor training for HCAHPS and in the HCAHPS Quality Assurance Guidelines, we clearly state the purpose and the proper use of HCAHPS data: Official HCAHPS Survey scores are published on the *Hospital Compare* website. CMS emphasizes that HCAHPS scores are designed and intended for use at the hospital level for the comparison of hospitals (designated by their CMS Certification Number) to each other. CMS does not review or endorse the use of HCAHPS scores for comparisons within hospitals, such as comparison of HCAHPS scores associated with a particular ward, floor, individual staff member, etc. to others. Such comparisons are unreliable unless adequate sample sizes are collected at the ward, floor, or individual staff member level. In addition, since HCAHPS questions inquire about broad categories of hospital staff (such as doctors in general and nurses in general rather than specific individuals), HCAHPS is not appropriate for comparing or assessing individual hospital staff members. Using HCAHPS scores to compare or assess individual staff members is inappropriate and is strongly discouraged by CMS.[222]

Comment: The majority of commenters supported CMS' proposal to remove the Communication About Pain questions from the HCAHPS Survey. A number of commenters who supported removal of the Communication About Pain questions also recommended CMS remove the questions earlier than proposed. Several commenters specifically recommended that CMS remove these questions immediately, asserting that the severity and urgency of the opioid crisis justifies immediate termination of the questions. One commenter recommended immediate removal of the Communication About Pain questions due to concerns that the subjective nature of the HCAHPS Survey, and the Communication About Pain questions, may not accurately represent hospital performance.

Other commenters recommended that CMS remove the Communication About Pain questions as soon as feasible, with one commenter specifically recommending removal effective with January 2020 discharges, due to the potential unintended consequences associated with continued use of the questions. These commenters further recommended that CMS first remove the Communication About Pain questions, then evaluate alternate methods of determining the impacts of removal and the value of collecting pain management data, rather than delaying removal in order to collect more data.

Response: We thank the commenters for their feedback and their support of our proposal to remove the Communication About Pain questions from the HCAHPS Survey. We believe that removing the Communication About Pain questions from the HCAHPS Survey will address potential confusion about the appropriate use of the HCAHPS Survey, is responsive to concerns regarding the public health issues arising from the opioid epidemic, and addresses the recommendation of the President's Commission on Combating Drug Addiction and the Opioid Crisis.

In addition, section 6104 of the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271) enacted on October 24, 2018, prohibits HCAHPS Surveys conducted on or after January 1, 2020 from including questions about communication by hospital staff with an individual about such individual's pain, unless such questions take into account, as applicable, whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for the treatment of pain. Section 6104 of the SUPPORT for Patients and Communities Act also states that the Secretary shall not include any measures based on the pain communication questions on the HCAHPS Survey in 2018 or 2019 on the *Hospital Compare* website and in the Hospital Value-Based Purchasing (VBP) Program.

We proposed to remove the Communication About Pain questions beginning with January 2022 discharges for the FY 2024 payment determination in an effort to avoid imposing undue burden on providers or their survey vendors to make necessary updates to surveys and data collection tools while also providing us additional time to assess the potential impact of using these questions in the HCAHPS Survey and the impact removal may have on responses to subsequent survey items (83 FR 37218 through 38220). Based on the stakeholder comments supporting removal of these questions, particularly those who requested we remove them immediately or as soon as possible, we assessed the feasibility of removing the questions as soon as operationally possible.

Upon further review of the operational timelines for making necessary updates to the HCAHPS Survey administration protocols, including conducting associated training of survey vendors and hospitals, and making updates to the CMS data submission warehouse and associated reporting tools, we found that it would be operationally feasible to remove the Communication About Pain questions earlier than we proposed. Furthermore, because the SUPPORT for Patients and Communities Act prohibits use of the Communication About Pain questions in HCAHPS Surveys conducted on or after January 1, 2020, it is appropriate to remove these questions from the HCAHPS Survey sooner than proposed—effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years. We also note that removing these questions effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years is responsive to commenters who recommended that we remove the Communication About Pain questions immediately or as soon as possible. Although we are removing the Communication About Pain questions, we will continue to consider the value of collecting data that relates to pain management. We will examine the effect of the absence of the Communication About Pain items on subsequent survey items once these items have been removed.

Therefore, in response to stakeholder feedback, to comply with the requirements of the SUPPORT for Patients and Communities Act, and upon further review of the operational considerations involved in removing the Communication About Pain questions, we are finalizing a modification to our proposal and will remove the questions effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years.

Comment: A few commenters also recommended that CMS remove the Communication About Pain questions from public reporting. One commenter further recommended that CMS not publicly report performance data on the Communication About Pain questions until further research on the impact and utility of the questions is performed. Another commenter recommended that while the Communication About Pain questions remain in the HCAHPS Survey, CMS should remove them from

[222] HCAHPS Quality Assurance Guidelines, V13.0. pp. 23–24, *available at: https://www.hcahpsonline.org/globalassets/hcahps/quality-assurance/2018_qag_v13.0.pdf.*

the scoring calculation to minimize potential adverse consequences.

Response: We appreciate the commenters' feedback regarding public reporting of the Communication About Pain questions. Due in part to stakeholder input urging us to remove the Communication About Pain questions immediately or as soon as possible, as discussed above, we have assessed the operational considerations and are finalizing a modification to our proposal to remove the questions effective with October 2019 discharges, which is the earliest we can feasibility implement removal of the Communication About Pain questions.

We are finalizing a modification of our public display proposal that we publicly reporting the Communication about Pain questions on *Hospital Compare* until October 2022 (comprising data from the first, second, third, and fourth quarters 2021) and then subsequently discontinue public reporting. Instead, we are finalizing that we will not publicly report data from the Communication about Pain questions at all because: We will no longer collect four quarters of CY 2019 Communication About Pain questions data; stakeholders' recommendations that we not publicly report the Communication About Pain data at all in order to avoid exacerbating any possible link between these questions and inappropriate prescribing practices; and the requirements of the SUPPORT for Patients and Communities Act, which prohibit publicly reporting on *Hospital Compare* any measures based on the Communication About Pain questions appearing in the HCAHPS Survey in 2018 or 2019. Not publicly reporting the data collected from the Communication About Pain questions also aligns with our efforts to mitigate any potential tie between the Communication About Pain questions and inappropriate opioid prescribing practices.

We note that in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38342), we finalized a delay in public reporting, such that hospital performance data on the refined Communication About Pain composite measure questions would not be publicly reported on the *Hospital Compare* website until October of CY 2020, using CY 2019 data. We stated that we would provide performance results, based on CY 2018 data on the refined Communication About Pain composite measure questions to hospitals in confidential preview reports, upon the availability of four quarters of data. We stated that we anticipated that these confidential preview reports would be available as early as July 2019. The effect of the modified policy we are finalizing in this final rule with comment period is that Communication About Pain data from the final CY 2019 reporting period (which would consist of three quarters of data, 1st quarter through 3rd quarter 2019) will also not be publicly reported.

However, we still plan to provide performance results based on these data to hospitals in confidential preview reports upon the availability of four quarters of CY 2018 data, as early as July 2019. Updated confidential reports will be provided on a quarterly basis with the availability of each new calendar quarter of data. The last confidential preview report containing the Communication About Pain questions data will reflect data from the fourth quarter of 2018 (October 1, 2018) through the third quarter of 2019 (September 30, 2019). We also note that the data collected from these questions will not be scored for purposes of CMS payments to hospitals, because the Hospital IQR Program is a pay-for-reporting, not pay-for-performance quality program and these questions are not part of the Hospital VBP Program.

Comment: Many commenters supported CMS' proposal to remove the current Communication About Pain questions from the HCAHPS Survey beginning with January 2022 discharges for the FY 2024 payment determination and subsequent years. Many commenters supported removing the Communication About Pain questions based on concerns about unintended consequences of their continued use, specifically that the questions may incentivize or pressure clinicians into inappropriately prescribing opioids. Some commenters asserted that removing these questions from the HCAHPS Survey would allow providers to address patients' pain in a safer manner, avoid inadvertently fostering an environment that could potentially promote the inappropriate use of opioids, and change perceptions about pain management. One commenter noted the Communication About Pain questions may also disincentivize the use of alternative methods of pain management in an effort to address patients' pain in the most efficient manner (that is, prescription of opioids). Another commenter specifically cited agreement with the recommendation of the President's Commission on Combating Drug Addiction and the Opioid Crisis in supporting removal of the Communication About Pain questions.

Several commenters supported removal of the Communication About Pain questions because the commenters' believe pain is subjective and is therefore, difficult to measure using a standardized set of survey questions. A number of other commenters supported removal of these questions due to their concern the questions correlate pain treatment with patient satisfaction, thereby creating unrealistic patient expectations regarding pain management. These commenters also expressed concern the questions contribute to an environment in which patients expect to be pain free, whereas the goal of pain therapy should be to appropriately manage, not eliminate, pain. One commenter specifically supported removal of these questions because the commenter believed the questions elevate pain too highly as a factor in patient satisfaction and, thereby, in hospital reimbursement. Another commenter supported removing the Communication About Pain questions because the commenter believed the approach to pain management is too complicated and unclear to be assessed using survey questions.

Response: We thank the commenters for their support. We are not aware of any scientific studies that support an association between scores on the Communication About Pain questions and opioid prescribing practices. In addition, we continue to believe that many factors outside the control of our quality program requirements may contribute to the perception of a link between the Communication About Pain questions and opioid prescribing practices, that pain management is an appropriate part of routine care that hospitals should manage and that pain management is an important concern for patients, their families, and their caregivers. Furthermore, we continue to believe the HCAHPS Survey is a valid and reliable measure of hospital quality that encourages hospitals to assess and improve patient experience. However, we believe that removing the Communication About Pain questions from the HCAHPS Survey will address potential confusion about the appropriate use of the HCAHPS Survey, is responsive to concerns regarding the public health issues arising from the opioid epidemic, and addresses both the recommendation of the President's Commission on Combating Drug Addiction and the Opioid Crisis and the prohibitions in the SUPPORT for Patients and Communities Act.

Comment: A few commenters encouraged CMS to remove the Communication About Pain questions from both payment programs (for example, the Hospital VBP Program) and public reporting programs (for

example, the Hospital IQR Program) given the concern about unintended consequences. One commenter stated that the Communication About Pain questions and related bonus payments led to an overuse of opioids and that removing the questions is important to addressing the current opioid crisis.

Response: To be clear, the Communication About Pain questions in the HCAHPS Survey are only used in the Hospital IQR Program. While the Hospital VBP Program uses HCAHPS Survey data to score the Patient and Community Engagement domain, it does not include the Pain Management dimension of the HCAHPS Survey—the predecessor of the current Communication About Pain questions. This dimension was removed from the Hospital VBP Program in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862) beginning with the FY 2018 program year. The Hospital VBP Program also does not use the current Communication About Pain questions. In addition, the Hospital IQR Program is a pay-for-reporting quality program, as opposed to a pay-for-performance quality program, and does not award incentive payments of any kind, including based on performance.

Comment: Several commenters acknowledged the lack of scientific evidence demonstrating an impact of the Communication About Pain questions on providers' prescribing practices, but supported removal of the questions out of an abundance of caution. One commenter noted that CMS programs can significantly influence trends in the opioid epidemic and agreed it was prudent, despite the lack of scientific evidence, to remove the Communication About Pain questions until a better understanding of the link between the questions and prescribing practices is reached. Another commenter acknowledged the value of patient satisfaction surveys but expressed concern about tying these surveys to publicly reported hospital ratings and accountability, and therefore, supported removal of the Communication About Pain questions from the HCAHPS Survey. Other commenters stated that the questions are only tenuously linked to improved quality of care, and that the questions are of limited value in their current state.

Response: We thank the commenters for their support. As noted above, we are not aware of any scientific studies that support an association between scores on the Communication About Pain questions and opioid prescribing practices. However, we believe that removing these questions from the HCAHPS Survey will address potential confusion about the appropriate use of the HCAHPS Survey, and is responsive to concerns regarding the public health concerns about the opioid epidemic as well as the provisions of the SUPPORT for Patients and Communities Act.

Comment: A few commenters supported removal of the Communication About Pain questions due to concerns regarding the wording and focus of the questions. One commenter expressed its belief the questions focus on the frequency of communication about pain management rather than the quality or impact of this communication on the patient's expectations and understanding about pain, while another commenter expressed concern that the questions fail to address population-specific challenges and variations in pain treatment regimens due to physician preference, patient behavior, or health care facility practices. A third commenter stated its belief the questions do not allow for a nuanced discussion of pain management and patient expectations. Another commenter asserted that the Communication About Pain questions create patient expectations that hospital personnel should always discuss pain and its treatment with patients, which the commenter believes can encourage inappropriate prescribing and unrealistic expectations. This commenter further asserted that the wording of the questions encourages providers to overemphasize pain when it may not be an issue for a particular patient.

One commenter supported removal of the Communication About Pain questions to preserve the Survey's integrity. Another commenter supported removal of the Communication About Pain questions due to concerns that the subjective nature of the HCAHPS Survey, and the Communication About Pain questions, may not accurately represent hospital performance. A third commenter expressed concern that including any questions about pain might cause patients who were unhappy about their pain treatment to provide negative responses to other, unrelated questions.

Response: We thank the commenters for their support of our proposal to remove the Communication About Pain questions from the HCAHPS Survey. We continue to believe the HCAHPS Survey as a whole, and the Communication About Pain questions, are valid and reliable measures of hospital quality that encourage hospitals to assess and improve patient experience. Further, we recognize that our programs may have an influence over trends in the opioid epidemic, which underscores our decision to remove the Communication About Pain questions from the HCAHPS Survey earlier than originally proposed. We believe that removing the Communication About Pain questions from the HCAHPS Survey out of an abundance of caution and to comply with the provisions of the SUPPORT for Patients and Communities Act will address potential confusion about the appropriate use of the HCAHPS Survey, and is responsive to concerns regarding the public health issues arising from the opioid epidemic.

Comment: A few commenters also noted the lack of National Quality Forum (NQF) endorsement as a reason to remove the Communication About Pain questions from the HCAHPS Survey and recommended that regardless of whether the questions are removed, CMS should submit the Communication About Pain questions for NQF endorsement.

Response: We note that, while the Hospital IQR Program is not statutorily limited to only using NQF-endorsed measures,[223] we consider NQF endorsement status when evaluating measures for adoption into the measure set. While the Communication About Pain questions are not currently NQF endorsed, because we are removing the Communication About Pain questions from the HCAHPS Survey in the Hospital IQR Program, we do not believe it prudent to submit the questions for NQF endorsement at this time. However, we will take commenters' feedback and recommendations into account as we continue to assess whether and how the Hospital IQR Program should assess communications about pain management. We note, however, that the HCAHPS Survey, in its entirety, is in fact NQF-endorsed (NQF #0166).[224]

Comment: A few commenters supported removal of the Communication About Pain questions because the commenters believe that it is inappropriate to tie pain management to hospital reimbursement. One commenter supported removal of the Communication About Pain questions because the commenter believed that incentivizing providers to base care on patient satisfaction increases healthcare costs. Another commenter expressed its belief that decreasing the incentive to prescribe opioids for pain management

[223] Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act.

[224] HCAHPS measure description and history, including NQF endorsement status, available at: *https://www.qualityforum.org/QPS/0166/*.

could reduce healthcare costs because opioid use can lead to a cascade of negative health effects that can increase lengths of stay and healthcare costs. Other commenters supported removal of the Communication About Pain questions because they believe it will help to reduce administrative burden and costs associated with data collection and reporting.

Response: As noted above, we continue to believe the HCAHPS Survey and Communication About Pain questions are reliable measures of hospital quality that encourage hospitals to assess and improve patient experience, and that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers. We believe the HCAHPS Survey is appropriate for use in CMS quality programs for public display of quality measurement data and tying hospital performance to Medicare reimbursement. However, out of an abundance of caution, and in the face of a nationwide epidemic of opioid overprescription, we believe that removal of the Communication About Pain questions from the HCAHPS Survey is warranted in order to resolve any perceived conflict between appropriate management of opioid use and patient satisfaction. Moreover, the SUPPORT for Patients and Communities Act prohibits inclusion of the Communication About Pain questions in HCAHPS Surveys conducted on or after January 1, 2020.

Comment: Many commenters did not support removal of the Communication About Pain questions based on concerns that removal of the questions may minimize the importance of appropriate communication about pain management in the hospital setting. Specifically, a number of commenters stated that pain management is a critical part of routine patient care on which hospitals should focus and an important concern for patients, their families, and their caregivers, and expressed concern that removing the Communication About Pain questions may result in potential negative consequences for both patients and providers. A few commenters expressed particular concern that removal of these questions could have a negative impact on the appropriate treatment of pain associated with complex chronic and end-of-life illnesses. Some of these commenters expressed concern that removing the Communication About Pain questions might lead hospitals and providers to place less importance on communicating with patients about their pain and pain management. One commenter also noted that The Joint Commission has included engaging patients in treatment decisions about their pain management as part of the pain assessment and management standards for 2018 accreditation standards.[225]

Some commenters who did not support removal of the pain questions urged CMS not to overlook the need to measure and evaluate how patient care is delivered and the role of appropriate communication about pain management during a hospital stay, including legitimate pain management using opioids in addition to other pain management methods. Other commenters asserted that removal of the pain questions would be tantamount to CMS refusing to acknowledge, or avoiding, the legitimate pain management needs of patients.

Response: We acknowledge commenters' concern that removal of the Communication About Pain questions may result in potential negative consequences for both patients and providers. We remain concerned, however, about the potential negative consequences resulting from retaining the Communication About Pain questions in the HCAHPS Survey, including confusion regarding the appropriate use of the questions. We believe these concerns, coupled with the severity and urgency of the nationwide opioid epidemic, warrant removing the Communication About Pain questions to relieve any potential pressure clinicians may feel to prescribe opioids in order to achieve higher scores on the HCAHPS Survey. By removing the Communication About Pain questions from the HCAHPS Survey, the Survey neither encourages nor discourages clinicians from communicating with their patients about their pain and how best to manage their pain as appropriate for the particular patient.

In addition, we disagree with commenters' assertions that removal of the Communication About Pain questions might lead hospitals and providers to place less importance on communication with their patients about their pain and pain management, or might lead to a negative impact on appropriate pain treatment, including treatment for pain associated with complex chronic and end-of-life illnesses. As a number of commenters noted, pain management is an appropriate part of routine patient care upon which hospitals should focus and an important concern for patients, their families, and their caregivers, and we do not believe removal of the Communication About Pain questions will necessarily result in hospitals no longer focusing on maintaining a high level of performance. Rather, we remain confident that hospitals will continue to focus on appropriate pain management, including communicating with their patients about pain, as part of their commitment to the patient experience and ongoing quality improvement efforts. In addition, as one commenter noted, engaging patients in treatment decisions about their pain management is required under the enhanced pain assessment and management requirements, applicable to all Joint Commission-accredited hospitals, effective January 1, 2018.[226]

With respect to commenters' requests that we not overlook the need to measure and evaluate how patient care is delivered and the role of appropriate communication about pain management during a hospital stay, including legitimate pain management using opioids in addition to other pain management methods, we reiterate that we remain dedicated to improving the quality of care provided to patients, including patients' experience in receiving care, and continue to consider the appropriate management of pain and communication between patients and their providers regarding pain as important aspects of care quality. As previously stated, we believe that removing the Communication About Pain questions will relieve any potential undue pressure on clinicians to prescribe opioids in order to achieve high patient satisfaction scores. We also believe that removing any such potential pressure on clinicians to prescribe opioids will ensure that providers can use their best judgment regarding pain management methods most appropriate for their patients, which may include non-opioid

[225] More information about The Joint Commission's new and revised pain assessment and management standards effective January 1, 2018 is available at: *https://www.jointcommission.org/joint_commission_enhances_pain_assessment_and_management_requirements_for_accredited_hospitals_/*.

[226] Ibid. The enhanced standards require that the hospital involves patients in the pain management treatment planning process through the following: Developing realistic expectations and measurable goals that are understood by the patient for the degree, duration, and reduction of pain; discussing the objectives used to evaluate treatment progress (for example, relief of pain and improved physical and psychosocial function); and providing education on pain management, treatment options, and safe use of opioid and non-opioid medications when prescribed. The enhanced standards also require, among other things, the hospital to analyze data collected on pain assessment and pain management to identify areas that need change to increase safety and quality for patients.

management methods. Moreover, the SUPPORT for Patients and Communities Act prohibits inclusion of the Communication About Pain questions in HCAHPS Surveys conducted on or after January 1, 2020.

Finally, we disagree with commenters' assertion that removing the Communication About Pain questions is tantamount to CMS' refusal to acknowledge, or avoiding, the legitimate pain management needs of patients. In the CY 2019 OPPS/ASC proposed rule (83 FR 37220), we solicited feedback regarding suggestions for other measures that would capture facets of pain management and related patient education, for instance, for collecting data about a hospital's pain management plan and providing that information back to consumers, and how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives. Numerous commenters responded to our requests for feedback, and we summarize these responses later in this discussion. We will take commenters' suggestions into consideration as we continue to consider how best to capture and assess facets of pain management through quality measurement.

Comment: A number of commenters did not support removal of the Communication About Pain questions due to the lack of empirical evidence that the questions are influencing providers to prescribe opiates or demonstrating a link between patient experience scores and opiate prescribing. One commenter further asserted that the Communication About Pain survey questions do not put more pressure on providers to prescribe opioids, but rather encourage providers to communicate about and address pain using multiple treatment methods.

Response: As previously stated, we are unaware of any empirical evidence demonstrating that failing to prescribe opioids lowers a hospital's HCAHPS Survey scores. While we intended for the Communication About Pain questions to encourage providers to communicate with patients about pain management-related issues, including non-opioid pain management therapies (82 FR 38330), out of an abundance of caution, and in the face of a nationwide epidemic of opioid overprescription, we believe that removal of the Communication About Pain questions is warranted in order to resolve any perceived conflict between appropriate management of opioid use and patient satisfaction. Moreover, because the SUPPORT for Patients and Communities Act prohibits the inclusion of such questions in HCAHPS Surveys conducted on or after January 1, 2020, removal of the Communication About Pain questions is required. We believe that removing these questions will resolve any potential confusion by ensuring providers can use their best judgment in appropriately managing patients' pain without any potential undue pressure stemming from fear of negative feedback on the HCAHPS Survey. We note that hospitals will continue to be required to administer the HCAHPS Survey comprised of the remaining 29 questions to eligible patients, and that hospital performance on HCAHPS Survey measures based on the remaining questions will continue to be publicly reported on *Hospital Compare.*

Comment: Some commenters opposed removal of the Communication About Pain questions because hospitals rely on the data for quality and performance improvement purposes. A few commenters asserted historical HCAHPS Survey data is one of the most effective tools hospitals have to improve patient experience of care. Some commenters noted that hospitals rely on HCAHPS Survey data to inform their quality and performance improvement efforts, including data from the Communication About Pain questions to assess how well they are discussing pain and communicating issues about pain management to patients.

A few commenters noted that removal of the questions would force hospitals to rely on their vendors for any pain communication composite calculations or benchmarks for internal assessment purposes, as opposed to the national and State averages provided by CMS under the HCAHPS Survey. These commenters recommended that CMS furnish providers with important care experience metrics by making current pain communication scores, along with national and State benchmarks, available through hospital preview reports, from October 2019 onward. Commenters further requested CMS include these scores in CMS data files for providers' benchmarking and analysis.

Response: We appreciate commenters' feedback about their concerns, experiences using HCAHPS Survey data, and recommendations. We acknowledge that removal of the Communication About Pain questions will eliminate our ability to calculate State and national averages, but we believe the importance of removing any perceived pressure of opioid overprescribing justifies removal of the questions during the national opioid epidemic. Moreover, the SUPPORT for Patients and Communities Act prohibits inclusion of the Communication About Pain questions in HCAHPS Surveys conducted on or after January 1, 2020.

As described above, we will provide each hospital with feedback on its own performance in confidential preview reports starting with four quarters of CY 2018 Communication About Pain question data, and then on a rolling four-quarter basis through the final quarter of CY 2019 Communication About Pain question data (that is, the 3rd quarter of 2019). These confidential reports will include State and national averages for the reporting periods when this measure is collected.

Comment: A number of commenters recommended that CMS retain the Communication About Pain questions in order to further investigate the relationship between these questions and opiate prescribing patterns, asserting that continued data collection would enable CMS to make a data-driven decision to retain or remove the questions based on available evidence. A few commenters questioned removal of the Communication About Pain questions based on concerns that the Communication About Pain questions were only recently implemented in January 2018. These commenters recommended that CMS retain the Communication About Pain questions in order to engage a broad range of stakeholders and assess their feedback regarding the use and impact of the Communication About Pain questions on opioid prescribing practices, hospital quality improvement efforts, and patient care. Other commenters recommended convening Technical Expert Panels and a pilot study to better assess the implications of removing the pain questions on patient care before removing the Communication About Pain questions.

Response: We thank commenters for their recommendations to postpone removal of the Communication About Pain questions until additional analyses can be performed. While we agree delaying removal of these questions would increase the amount of data available to potentially assess the questions' effect on physician prescription practices and the link between patient experience scores and opiate prescribing, we believe concerns regarding the potential negative consequences of retaining the questions and public health concerns about the opioid epidemic outweigh the benefits of additional data collection. We believe the importance of removing any

perceived pressure of opioid overprescribing justifies removal of the questions during the national opioid epidemic. Moreover, the SUPPORT for Patients and Communities Act prohibits inclusion of the Communication About Pain questions in HCAHPS Surveys conducted on or after January 1, 2020. For these reasons, as discussed above, we are finalizing a modification of our proposal and are removing the Communication About Pain questions beginning with October 2019 discharges for the FY 2021 payment determination and subsequent years.

Comment: Many commenters who did not support removal of the Communication About Pain questions due to the importance of capturing pain management experience data also recommended that CMS delay public reporting on the questions beyond October 2020 to allow further time for additional assessment of the questions. A number of these commenters recommended that CMS continue to test the questions and delay public reporting until the questions are valid, reliable, and do not pose a risk of unintended consequences. A few commenters also supported delaying public reporting based on their concerns about the absence of any evidence demonstrating a relationship between the use of the Communication About Pain questions and opioid prescribing behavior.

Response: We thank commenters for their recommendations. We continue to believe the HCAHPS Survey as a whole, and the Communication About Pain questions, are valid and reliable measures of hospital quality that encourage hospitals to assess and improve patient experience. However, we believe that removing the Communication About Pain questions from the HCAHPS Survey during the national opioid epidemic will remove any perceived pressure of opioid overprescribing, and will address potential confusion about the appropriate use of the HCAHPS Survey. Therefore, as stated above, upon consideration of the comments received and public health concerns about the opioid epidemic, as well as to comply with the SUPPORT for Patients and Communities Act, we will not publicly report data collected from the Communication About Pain questions.

Comment: A number of commenters responded to CMS' request for feedback in the proposed rule (83 FR 37220) regarding whether it would be valuable for CMS to issue guidance suggesting that hospitals do not administer any surveys with pain-related questions, including adding hospital-specific supplemental items to HCAHPS, as well as the potential implementation of a third party quality assurance program to assure that hospitals are not misusing survey data by creating pressure on individual clinicians to provide inappropriate clinical care. A few commenters recommended that CMS consider issuing guidance to providers and hospitals regarding appropriate use of the HCAHPS Survey, specifically against the disaggregation of HCAHPS Survey data. These commenters stated their belief that clearer survey use guidance would mitigate inappropriate use of survey results, such as using disaggregated data to assess providers' performance, to compare performance across providers or wards, and/or to influence provider performance by tying disaggregated survey results to individual clinician compensation. One commenter asserted that CMS guideline adherence works best when an HCAHPS Survey vendor provides hospitals and healthcare systems with clear communication and interpretation of those guidelines, and therefore recommended against implementation of an HCAHPS Survey-specific quality assurance program. This commenter recommended that CMS consider future implementation of a third-party quality assurance program for all CMS-mandated CAHPS surveys.

Other commenters recommended against CMS disallowing administration of supplemental pain management related questions alongside the HCAHPS Survey. These commenters noted pain remains one of the most important aspects of a patient's experience of care, that hospitals rely on this survey-based information for research and evaluation regarding their quality and efficacy of care, and that disallowing these supplemental questions would effectively omit a critical care experience factor from hospitals' quality improvement efforts.

Response: We thank the commenters for their feedback and will take these recommendations into consideration as we move forward with the HCAHPS Survey.

Comment: A number of commenters responded to CMS' request for feedback regarding suggestions for other measures that would capture facets of pain management and related patient education, and that would provide that information back to consumers, as well as CMS' request for feedback regarding how other measures could take into account provider-supplied information on appropriate pain management and whether patients are informed about the risks of opioid use and about non-opioid pain management alternatives. Many commenters encouraged CMS to engage with stakeholders, including hospitals, clinicians, experts in pain management and palliative care, measure developers, researchers, the NQF, and the Measure Applications Partnership (MAP) to explore a range of approaches to assessing how healthcare systems and hospitals are addressing pain management, including further revisions to the pain questions in HCAHPS Survey and the use of other measurement methods, including pain assessments that are more sensitive to beneficiaries' needs.

Several commenters recommended that CMS engage in further research on the current version of the Communication About Pain questions, including assessing the potential tie between the questions and opioid prescribing practices. A few commenters provided specific recommendations for improving pain management assessment within the HCAHPS Survey. Some commenters recommended that CMS revise the current pain management questions to focus more on alternative pain management methods, such as ice packs and over-the-counter pain medication, and to better assess whether the patient was given sufficient guidance on how to manage pain post-discharge. Another commenter recommended that CMS develop new pain management questions focused on pain management processes and evidence-based standards of care rather than patient-reported outcomes. A third commenter recommended that CMS develop alternate questions assessing the role and behaviors of different clinicians in a patient's pain management because the commenter believed these alternatives are more objective than the current Communication About Pain questions and would provide a better picture of the assessment and treatment undertaken by the clinician for the patient's pain. Another commenter encouraged CMS to conduct additional research on pain-related survey questions and prescribing practices in emergency departments. One commenter recommended that CMS continue to collect the current Communication About Pain questions while evaluating potential new measures due to the importance of continuing to collect data on hospitals' communication about pain management as a critical component of patient experience and because more time is needed to collect feedback on potential alternatives.

One commenter suggested CMS evaluate assessing communication about pain management within the context of specific care episodes because these

assessments could focus on the use of targeted pain management modalities, unlike the global HCAHPS Survey. This commenter further recommended that CMS focus on developing high-priority pain measures that can improve functional assessment scores with reduced opioid use. Another commenter recommended that CMS evaluate the use of patient-reported outcome measures to assess pain management and communication about pain because the commenter believed these types of measures would provide hospitals with valuable experience of care data relative to the investment required to update infrastructure and workflow investment. A third commenter expressed support for development of meaningful measures of pain management but urged caution about the potential for measures to create undue barriers to access to appropriate pain medication for patients suffering from chronic pain and therefore recommended that CMS strive to make measures more sensitive to patients' disease state. Another commenter encouraged additional research and measure development specific to emergency department care and emergency nursing.

Response: We appreciate the feedback from commenters and will take these comments into consideration as we continue to consider how best to capture and assess facets of pain management through quality measurement, including the role of appropriate communication about pain during a hospital stay, informing patients about the risks associated with the use of opioids, and educating patients on non-opioid alternative pain management methods. As stated above, we believe that removing the Communication About Pain questions from the HCAHPS Survey out of an abundance of caution during the national opioid epidemic will help to address any potential confusion about the appropriate use of the HCAHPS Survey by relieving any potential pressure or undue influence on clinicians' opioid prescribing practices.

Comment: Some commenters recommended that CMS focus on mitigating any unintended consequences of pain management assessment before developing new measures, and further recommended against the adoption of measures that increase administrative burden and/or are not linked to improved outcomes. These commenters also recommended that CMS enable hospitals and physicians to monitor the administration of opioids and promote their evidence-based use through programs that are tailored to the needs of the hospital and its patient population. One commenter specifically recommended against development of pain management-specific measures because the commenter believes a set of measures designed to be applied universally would downplay critical factors that are necessary to create individualized pain management plans. One commenter requested a model of the impact of the removal of the Communication About Pain questions on overall HCAHPS scores and urged CMS to carefully balance the need to remove the questions with the need to retain an important component of patient experience.

Response: We appreciate the feedback from commenters and will take these comments into consideration as we continue to consider how best to capture and assess facets of pain management through quality measurement, including the role of appropriate communication about pain during a hospital stay, informing patients about the risks associated with the use of opioids, and educating patients on non-opioid alternative pain management methods. We will continue to consider unintended consequences of pain management assessment and we encourage hospitals to monitor the administration of opioids through programs that are tailored to the needs of the specific hospitals and patient populations. We do not anticipate that removing the Communication About Pain questions would impact the overall HCAHPS scores. We note that the data collected from the Communication About Pain questions will not be scored for purposes of CMS payments to hospitals, because the Hospital IQR Program is a pay-for-reporting not pay-for-performance quality program. Further, we note that the data from the Communication About Pain question will not be publicly reported. Our decision to remove the Communication About Pain questions from the HCAHPS Survey was based upon careful consideration of the importance of addressing patients' experience, stakeholder feedback, and the nationwide opioid epidemic.

Comment: A few commenters recommended that instead of removing the Communication About Pain questions, CMS consider incentivizing alternative pain management methods. Specifically, one commenter recommended that CMS consider alternate ways to ensure adequate patient awareness of non-opioid alternative treatments because the commenter believed that in the future there will be more ways to treat chronic and acute pain. Another commenter expressed the belief that there is a need for additional funding or other incentives to increase research supporting evidence-based practices around effective pain assessment and intervention and to develop operational guidelines and clinical practice standards for use in hospitals. A few commenters who supported both the importance of assessing patient experience, as well as of avoiding incentivizing inappropriate opioid prescribing, urged CMS to ensure that CMS does not adopt policies that could impede access to medication for patients who legitimately need opioids.

Response: We appreciate the feedback from commenters and will take these comments into consideration as we continue to consider how best to capture and assess facets of pain management through quality measurement, including the role of appropriate communication about pain during a hospital stay, informing patients about the risks associated with the use of opioids, and educating patients on non-opioid alternative pain management methods.

After consideration of the public comments we received, and as required by the SUPPORT for Patients and Communities Act, we are finalizing a modified version of our proposals regarding removal of the Communication About Pain questions from the HCAHPS Survey in the Hospital IQR Program. Instead of removing the questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years as proposed, we are finalizing removing them effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years. In addition, instead of publicly reporting the data from October 2020 until October 2022 and then subsequently discontinuing public reporting as proposed, we are finalizing that we will not publicly report the data collected from the Communication About Pain questions at all.

XVII. Additional PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program Policies

A. Background

Section 1866(k)(1) of the Act requires that, for FY 2014 and each subsequent fiscal year, hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program strives to put patients first by ensuring they, along with their clinicians, are empowered to make decisions about their own health care using data-driven insights that are increasingly aligned with meaningful quality measures. To this end, we support technology that reduces burden and allows clinicians to focus on providing high quality health care to their patients. We also support innovative approaches to improve the quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when participating in CMS programs. In combination with other efforts across the Department of Health and Human Services (HHS), we believe the PCHQR Program incentivizes PCHs to improve their health care quality and value, while giving patients the tools and information needed to make the best decisions.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425); and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624).

B. Retention of Two Safety Measures in the PCHQR Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41611 through 41616), we finalized the removal of four previously finalized measures and finalized one new quality measure for the FY 2021 program year and subsequent years. We also discussed our proposal in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503) to remove two National Healthcare Safety Network (NHSN) chart-abstracted measures from the PCHQR Program beginning with the FY 2021 program year under proposed removal Factor 8, ''the costs associated with the measure outweigh the benefit of its continued use in the program.'' The measures we had proposed to remove under this removal factor are:

- NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138); and
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139).

We noted that we had first adopted the CAUTI and CLABSI measures for the FY 2014 program year in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53557 through 53559), and we referred readers to that final rule for a detailed discussion of the measures. We also stated that we had proposed to remove these measures from the PCHQR Program based on our belief that removing these measures would reduce program costs and complexities associated with the use of these data by patients in decision-making. We also believed the costs, coupled with the high technical and administrative burden on PCHs associated with collecting and reporting this measure data, outweighed the benefits of the continued use of the CAUTI and CLABSI measures in the program. Further, we noted that it has become difficult to publicly report these measures due to the low volume of data produced and reported by the small number of facilities participating in the PCHQR Program and the corresponding lack of an appropriate methodology to publicly report these data.

We stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41613) that we had invited public comment on our proposals to remove the CAUTI and CLABSI measures from the PCHQR Program beginning with the FY 2021 program year. We also stated that we would defer making a final decision on the removal or retention of the CAUTI and CLABSI measures from the PCHQR Program in order to conduct additional data analyses to assess measure performance based on new information provided by the CDC which was not available at the time we had proposed the removal of these measures. Lastly, we stated that we wished to evaluate those data for trends that link positive improvements (that is, a decrease in the reporting burden and/or cost, and/or demonstrated feasibility for public reporting) to these measures. We also noted that we would reconcile the public comments we received in future rulemaking.

Comment: Many commenters supported the proposed removal of the CAUTI and CLABSI measures from the PCHQR Program. Commenters indicated that an appropriate statistical method to publicly report the data has not been identified and believed that these definitional and statistical issues may hamper the cancer hospitals' ability to identify opportunities for internal performance improvement activities related to these measures. Commenters also noted that the low number of PCHs, the heterogeneous makeup of the hospitals, and the nationwide dispersion of the sites make it difficult to provide meaningful comparisons for consumers. Commenters supported CMS' efforts in streamlining the PCHQR Program measure set, consistent with CMS' commitment to using a smaller set of more meaningful measures and reducing paperwork and reporting burden on providers. Nevertheless, given the potential negative impact of health-care acquired infections (HAIs) on patients, particularly for the cancer patient population, commenters encouraged the CDC and CMS to continue to work collaboratively with professional societies to standardize definitions, reporting, and sharing of data to foster performance improvement in these areas.

Response: We thank the commenters for their support. We will continue to work collaboratively to standardize definitions, and to develop a sufficient reporting mechanism for quality metrics that assess the impact of HAIs on patients, particularly for the cancer patient population. However, for the reasons discussed in more detail below, we are not finalizing our proposals to remove the CAUTI and CLABSI measures from the PCHQR Program.

Comment: Some commenters did not support the proposed removal of the CAUTI and CLABSI measures from the PCHQR Program, asserting that the application of proposed removal Factor 8 was inadequate for measure removal because consumers' needs have not been appropriately factored into the value assessment of the measures. Commenters specifically expressed concern that removing these measures might inappropriately deemphasize the importance of patient safety in quality care delivery. The commenters further questioned whether cost is the direct driving factor for the low volume of reporting on the CAUTI and CLABSI measures. Commenters also noted that because cancer hospitals will still be required to complete NHSN reporting for other measures, removal of the CAUTI and CLABSI measures would not necessarily lead to significant burden reduction. Lastly, commenters encouraged CMS to continue to work with the measures' developer to consider alternative methodologies for publicly reporting the measure data.

Response: We thank the commenters for their feedback. We believe the primary benefit of a measure's use in the PCHQR Program is to empower consumers through incentivizing the provision of high quality care and providing publicly reported data

regarding the quality of care available for use in making decisions about their care. Therefore, we intend to consider the benefits, especially to patients and their families, when evaluating measures under measure removal Factor 8, which we finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611). We emphasize that consumers' needs and interests are factored into the value assessment of measures prior to any proposal to remove a measure from the PCHQR Program, and further note that we regularly solicit consumer feedback on the PCHQR Program via public comment periods and education and outreach activities, and that this feedback informs our policy development efforts.

At the time that we proposed to remove the CAUTI and CLABSI measures from the PCHQR Program, the available performance data did not enable us to assess PCH performance relative to oncology unit performance in other care settings. In addition, CDC's previous analytic work used to develop the rebaselined predictive models had demonstrated that PCH status was not a significant predictor for either CAUTIs or CLABSIs. Since that time, we have conducted our own updated analyses regarding the continued use of the CAUTI and CLABSI measures in the PCHQR Program using updated CDC data. Although CDC had previously believed that oncology unit locations, including those in PCHs, had a higher incidence of infections than other types of units in acute care hospitals, CDC now believes, after controlling for location type, that oncology unit locations in PCHs do not have a higher incidence of infection than oncology units within other acute care hospitals. CDC's updated analysis also produced a consistent finding that cancer hospital status was not a significant risk factor in any of the device-associated HAI risk models, including those used for CLABSI and CAUTI.[227] We believe that these results indicate that reporting PCH CAUTI and CLABSI performance measure data is just as important as reporting acute care hospital CAUTI and CLABSI performance measure data.

We are aware that the CLABSI and CAUTI measures specifications were recently updated to use new standard infection ratio (SIR) calculations that can be applied to cancer hospitals, including PCHs. This SIR calculation method is different than the current CLABSI and CAUTI measure methodology, which provides raw location-stratified rates. We are also aware that there may be concern that the CAUTI and CLABSI data calculated under the current methodology may inaccurately appear to show lower performance among PCHs than the performance reported by acute care hospitals that are reporting CLABSI and CAUTI data under the newly updated methodology. We believe this recent update[228] of the CAUTI and CLABSI measures addresses these concerns. Specifically, the updates include rates that are stratified by patient care locations within PCHs, and no predictive models or comparisons are used in these rate calculations. We intend to propose to adopt these updated versions of the CLABSI and CAUTI measures in future rulemaking but believe that, until that time, the importance of emphasizing patient safety in quality care delivery justifies retaining the current versions of the CLABSI and CAUTI measures in the PCHQR Program. Despite the fact that infection rates are not higher in the PCHs, we believe it is important to measure CLABSI and CAUTI in this setting. However, we will work closely with the CDC to assess the updated risk-adjusted versions of CAUTI and CLABSI, and evaluate the data provided in the form of SIRs for each PCH, for the purposes of future program implementation and public reporting.

After consideration of the public comments we received, and consideration of the most recent information provided by the CDC, we are not finalizing our proposals to remove the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) from the PCHQR measures beginning with the FY 2021 program year. We agree with the conclusions drawn from the CDC's data analyses, which demonstrate that reporting PCH CAUTI and CLABSI performance measure data is just as important as reporting acute care hospital CAUTI and CLABSI performance measure data. Further, we believe that these measures have the potential to provide beneficiaries with valuable information on PCH performance in avoiding hospital-acquired infections and improving patient safety. However, for the reasons discussed in section XVII.C.2. of this final rule with comment period, we are continuing to defer public reporting of these measure data.

We believe this approach most effectively balances the needs of the PCHQR Program and the importance of collecting patient safety data while taking into consideration the impact on the 11 PCHs of reporting raw data to CMS. We hope to introduce the refined CAUTI and CLABSI measures with adequate risk adjustment into the PCHQR Program in the near future. We note any such change will be made via rulemaking, and that we will solicit input from the Measures Application Partnership (MAP) to garner multi-stakeholder input on the updated versions prior to proposing to adopt these refined measures.

The table below summarizes the PCHQR Program measure set for the FY 2021 program year:

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[227] SIR Guide: August 2018 Update. Available at: *https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf*.

[228] NHSN Patient Safety Component Manual: January 2018 Update. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf*.

FY 2021 PCHQR Program Measure Set

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI)		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium Difficile* Infection (CDI) Outcome Measure
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus Aureus* Bacteremia Outcome Measure
HCP	0431	National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel
Clinical Process/Oncology Care Measures		
N/A	0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care		
HCAHPS	0166	HCAHPS
Clinical Effectiveness Measure		
EBRT	1822	External Beam Radiotherapy for Bone Metastases

Short Name	NQF Number	Measure Name
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A*	3188	30-Day Unplanned Readmissions for Cancer Patients

* Measure finalized for adoption for the FY 2021 program year and subsequent years.

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C. Continued Deferment of Public Display of the NHSN Measures

1. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

2. Deferment of Public Display of National Healthcare Safety Network (NHSN) Measures

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41622), we indicated that all PCHs are reporting Colon and Abdominal Hysterectomy SSI, MRSA, CDI, and HCP data to the NHSN under the PCHQR Program. In 2016, the CDC announced that HAI data reported to NHSN for 2015 will be used as the new baseline, serving as a new ''reference point'' for comparing progress.[229] The results of the rebaselining allow for year-to-year comparisons beginning with 2015 data; beginning with FY 2019, we will have more than 2 years of comparable data available for evaluation. We are currently still evaluating the data resulting from the rebaselining to properly assess trends.[230] Therefore, in that final rule (83 FR 41622), we finalized a modification of our proposal to delay public reporting of data for the SSI, MRSA, CDI, and HCP measures until CY 2019. Based on stakeholder feedback, we finalized a policy to provide stakeholders with performance data as soon as practicable (that is, if useable data is available sooner than CY 2019, we will publicly report it on the *Hospital Compare* website via the next available *Hospital Compare* release).

As discussed above, we are not finalizing our proposal to remove the CAUTI and CLABSI measures. However, we will continue to defer public reporting for the CAUTI and CLABSI measures as indicated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38423). Based on our intent to propose to adopt the revised versions of the measures in the PCQHR Program in future rulemaking, we are continuing to evaluate the performance data for the updated versions of the CAUTI and CLABSI measures to draw conclusions about their statistical significance, in accordance with current risk adjustment methods defined by CDC. For these reasons, we are finalizing that we will provide stakeholders with performance data for the CAUTI and CLABSI measures as soon as practicable.

3. Update on Public Display of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57187 through 57188), we stated that we would publicly report the risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR) for the Admissions and Emergency Department (ED) Visits for the Patients Receiving Outpatient Chemotherapy measure for all participating PCHs with 25 or more eligible patients per measurement period to maintain a reliability of at least 0.4 (as measured by the interclass correlation coefficient, (ICC)). We also noted that if a PCH did not meet the 25-eligible patient threshold, we would include a footnote on the *Hospital Compare* website indicating that the number of cases is too small to reliably measure that PCH's rate, but that these patients and PCHs would still be included when calculating the national rates for both the RSAR and RSEDR. Lastly, we indicated that to prepare PCHs for public reporting, we would conduct a confidential national reporting (dry run) of measure results prior to public reporting.

We recently completed the confidential national reporting (dry run) for this measure and are currently assessing the results to ensure data accuracy and completeness. We intend to propose a timeframe for public reporting of this measure in the FY 2020 IPPS/LTCH PPS proposed rule.

4. Summary of Public Display Requirements for the FY 2021 Program Year

Our public display policies for the FY 2021 program year are shown in the following table:

[229] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

[230] Rebase line Timeline FAQ Document. Available at: *https://www.cdc.gov/nhsn/pdfs/rebaseline/faq-timeline-rebaseline.pdf.*

Public Display Requirements for the FY 2021 Program Year

Summary of Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166) • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)	2016 and subsequent years
• External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)	2017 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	As soon as practicable
• CLABSI (NQF #0139) • CAUTI (NQF #0138)	Deferred

XVIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC proposed rule (83 FR 37220), for CY 2019, we proposed to change the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we would flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). We requested public comments on this proposed change to the OPPS Addenda A, B, and C for CY 2019.

We did not receive any public comments regarding the proposed CY 2019 format changes for the OPPS Addenda A, B, and C. Therefore, for CY 2019, we are finalizing our proposal to add an additional column entitled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year for which the copayment will be capped at the inpatient deductible amount.

To view the Addenda to this final rule with comment period pertaining to CY 2019 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''1695–FC'' from the list of regulations. All OPPS Addenda to this final rule with comment period are contained in the zipped folder entitled ''2019 OPPS 1695–FC Addenda'' at the bottom of the page. To view the Addenda to this final rule with comment period pertaining to CY 2019 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''1695–FC'' from the list of regulations. All ASC Addenda to this final rule with comment period are contained in the zipped folders entitled ''Addendum AA, BB, DD1, DD2, and EE.''

XIX. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the CY 2019 OPPS/ASC proposed rule (83 FR 37720), we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

B. ICRs for the Hospital OQR Program

1. Background

The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital IQR Program. We refer readers to the CY 2011 through CY 2018 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; and 82 FR 59476 through 59479, respectively) for detailed discussions of Hospital OQR Program information collection requirements we have previously finalized. The information collection requirements associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109. Below we discuss only the changes in burden that will result from the newly finalized policies in this final rule with comment period.

In section XIII.B.4.b. of the proposed rule, we proposed to remove a total of 10 measures. Specifically, beginning with the CY 2020 payment determination, we proposed to remove: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we proposed to remove: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; (8) OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; (9) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use; and (10) OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. However, after consideration of public comments we received, in this final rule with comment period we are not finalizing our proposals to remove two measures: OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2021 payment determination. The reduction in burden associated with our finalized policies is discussed below in sections XIX.B.3. and 4. of this final rule with comment period.

In section XIII.D.2. of this final rule with comment period, we are finalizing our proposal to update the frequency with which we will release HOPD Specifications Manuals, with modification, such that instead of releasing the full manual once or twice a year, as proposed, we would release specifications manuals every 12 months beginning with CY 2019 and for subsequent years and release addenda (specific updates rather than full manual releases) as necessary. In section XIII.C.2. of this final rule with comment period, beginning with the CY 2020 payment determination, we are finalizing our proposal to remove the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and to update 42 CFR 419.46(a) to reflect these policies. As discussed below, we do not expect these finalized policies to affect our collection of information burden estimates.

2. Update to the Frequency of Releasing Hospital Outpatient Quality Reporting Specifications Manuals Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this final rule with comment period, we are finalizing our proposal, with modification, to update the frequency with which we will release Hospital Outpatient Quality Reporting Specifications Manuals, with modification such that instead of releasing the full manual once or twice each year, as proposed, we will release the Specifications Manuals once every 12 months and release addenda as necessary, beginning with CY 2019 and for subsequent years. We anticipate that this change will reduce hospital confusion, as releasing fewer manuals per year reduces the need to review updates as frequently as was previously necessary. However, because this change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not expect a change in the information collection burden experienced by hospitals.

3. Estimated Burden of Hospital OQR Program Newly Finalized Policies for the CY 2020 Payment Determination and Subsequent Years

a. Removal of the Notice of Participation (NOP) Form Requirement

In section XIII.C.2.b. of this final rule with comment period, beginning with the CY 2020 payment determination, we are finalizing our proposal to remove the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals will need to: (1) Register on the QualityNet website; (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are finalizing our proposal to update 42 CFR 419.46(a) to reflect these policies. We have previously estimated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75171) that the burden associated with administrative requirements including completing program requirements, system requirements, and managing facility operations is 42 hours per hospital or 138,600 hours across 3,300 hospitals. We believe that removal of the NOP requirement will reduce administrative burden experienced by hospitals by only a nominal amount, as it is not required every year, but only at the start of a hospital's participation. As a result, this finalized policy does not influence our information collection burden estimates.

b. Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are finalizing our proposal to remove the OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a National Healthcare Safety Network (NHSN) measure, is accounted for under a separate information collection request, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program.

4. Estimated Burden of Hospital OQR Program Newly Finalized Policies for the CY 2021 Payment Determination and Subsequent Years

a. Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are finalizing our proposal to remove one chart-abstracted measure for the CY 2021 payment determination and subsequent years: OP–5: Median Time to ECG. With regard to chart-abstracted measures for which patient-level data is submitted directly to CMS, we have previously estimated it would take 2.9 minutes, or 0.049 hours, per measure to collect and submit the data for each submitted case (80 FR 70582). In addition, based on the most recent data, we estimate that 947 cases are reported per hospital for chart-abstracted measures. Therefore, we estimate that it will take approximately 46 hours (0.049 hours × 947 cases) to collect and report data for each chart-abstracted measure. Accordingly, we believe that the removal of this chart-abstracted measure for the CY 2021 payment determination will reduce burden by 151,800 hours (46 hours × 3,300 hospitals) and $5.6 million (151,800 hours × $36.58 [231]).

b. Removal of Measures Submitted Via a Web-Based Tool for the CY 2021 Payment Determination and Subsequent Years

While we proposed to remove five measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years, in section XIII.B.4.b. of this final rule with comment period, we are only finalizing our proposals to remove three measures: (1) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (2) OP–17: Tracking Clinical Results between Visits; and (3) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. In section XIII.B.4.b. of this final rule with comment period, we are not finalizing our proposals to remove the following web-based measures for the CY 2021 payment determination and subsequent years: OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. Therefore, we are revising the initially estimated burden reduction from the CY 2019 OPPS/ASC proposed rule.

As we stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70582), we estimate that hospitals spend approximately 10 minutes, or 0.167 hours, per measure to report web-based measures. Accordingly, we believe that the removal of OP–12, OP–17, and OP–30 for the CY 2021 payment determination will reduce burden by 0.501 hours per hospital (3 measures × 0.167 hours per measure) and 1,653 hours (0.501 hours × 3,300 hospitals) across 3,300 hospitals. In addition, we estimate that OP–30 requires 25 additional minutes (0.417 hours) per case per measure to chart-abstract and that hospitals would each abstract 384 cases per year for this measure. This number is based on previous analysis (78 FR 75171) where we estimated that each of the approximately 3,300 responding hospitals will have a case volume adequate to support quarterly sample sizes of 96 cases, for a total of 384 cases (96 cases per quarter × 4 quarters) to be abstracted by each hospital annually. Therefore, we estimate an additional burden reduction of 528,422 hours (3,300 hospitals × 0.417 hours × 384 cases per measure) for all participating hospitals for OP–30. In total, we estimate a burden reduction of 530,075 hours (1,653 hours for web submission + 528,422 hours for chart-abstraction of OP–30) and $19.4 million (530,075 hours × $36.58) due to the removal of three web-based measures from the Hospital OQR Program for the CY 2021 payment determination and for subsequent years.

c. Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are finalizing our proposals to remove three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. Claims-based measures are derived through analysis of administrative claims data and do not require additional effort or burden on hospitals. As a result, we do not expect these removals to affect collection of information burden for the CY 2021 payment determination.

In total for the CY 2021 payment determination, we expect the information collection burden will be reduced by 151,800 hours due to the removal of one chart-abstracted measure, and 530,075 hours due to the removal of three measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 681,875 hours (151,800 hours for the removal of one chart-abstracted measure + 530,075 hours for the removal of three web-based measures) and $24.9 million (681,875 hours × $36.58) for the CY 2021 payment determination.

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, and CY 2018 OPPS/ASC final rules with comment period (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; and 82 FR 59479 through 59481, respectively) for detailed discussions of the ASCQR Program information collection requirements we have previously finalized. The information collection requirements associated with the ASCQR Program are currently approved under OMB control number 0938–1270. Below we discuss only the changes in burden that would result from the newly finalized provisions in this final rule with comment period.

While we proposed to remove eight measures, in section XIV.B.3.c. of this final rule with comment period, we are only finalizing the removal of two measures: One measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel, and one measure beginning with the CY 2021 payment determination: ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. We expect these finalized policies will reduce the overall burden of reporting data for the ASCQR Program, as discussed below. In section XIV.B.3.c. of this final rule with comment period, we are not finalizing our proposal to remove ASC–9: Endoscopy/Polyp

[231] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized an hourly labor cost to hospitals of $36.58 and specified that this cost included both wage ($18.29) and 100 percent overhead and fringe benefit costs (an additional $18.29). The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients beginning with the CY 2021 payment determination and ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. In addition, we are not finalizing our proposals to remove ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission, but are instead retaining the measures in the ASCQR Program and suspending their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the measures.

2. Estimated Burden of ASCQR Program Newly Finalized Policy Beginning With CY 2020 Payment Determination and Subsequent Years: Removal of ASC–8

In section XIV.B.3.c. of this final rule with comment period, we are finalizing the removal of one measure beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. Data for ASC–8 are submitted via a non-CMS online data submission tool, to the NHSN. However, we note that the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program OMB control number.

3. Estimated Burden of ASCQR Program Newly Finalized Measure Removals for the CY 2021 Payment Determination

While we proposed to remove seven measures beginning with the CY 2021 payment determination, in section XIV.B.3.c. of this final rule with comment period, we are only finalizing our proposal to remove one measure: ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. In section XIV.B.3.c. of this final rule with comment period we are not finalizing our proposals to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. In addition, we are not finalizing our proposals to remove ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission, but are instead retaining the measures in the ASCQR Program and suspending their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the measures. Therefore, we are revising the estimated information collection burden changes from the estimates included in the CY 2019 OPPS/ASC proposed rule (83 FR 37222).

a. Removal of One Chart-Abstracted Measure for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this final rule with comment period, we are finalizing the removal of one chart-abstracted measure from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. We believe 3,937 ASCs will experience a reduction in information collection burden associated with our finalized policy to remove ASC–10 from the ASCQR Program measure set.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79864), we finalized our estimates that each participating ASC would spend 0.25 hours (15 minutes) per case per measure per year to collect and submit the required data for ASC–10. We estimate that the average number of patients per ASC is 63 based on the historic average. In addition, we estimate the total annual information collection burden per ASC to be 15 hours and 45 minutes (15.75 hours) per measure (0.25 hours × 63 cases). Therefore, for ASC–10, we estimate the total annualized information collection burden to be 62,008 hours (3,937 ASCs × 15.75 hours per ASC) and $2,268,244 (3,937 ASCs × 15.75 hours per ASC × $36.58 per hour[232]). Therefore, we estimate a total reduction in information collection burden of 62,008 hours and $2,268,244 as a result of our removal of ASC–10 from the ASCQR Program measure set for the CY 2021 payment determination. The reduction in information collection burden associated with these requirements is available for review and comment under OMB control number 0938–1270.

D. ICRs for the Update to the HCAHPS Survey Measure in the Hospital IQR Program

As described in section XVI. of this final rule with comment period, we are finalizing a modified version of our proposals regarding the Communication About Pain questions from the HCAHPS Survey in the Hospital IQR Program. Instead of removing the questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years as proposed, we are finalizing to remove them effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years. In addition, instead of publicly reporting the data in October 2022 and then subsequently discontinuing as proposed, we are finalizing that we will not publicly report the data collected from the Communication About Pain questions at all.

While we anticipate that the removal of these questions will reduce the burden associated with reporting this measure, as further discussed below, the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. For discussion of the burden estimate for the Hospital IQR Program under OMB control number 0938–1022, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41689 through 41694). For details on the burden estimate specifically for the HCAHPS Survey, including use of the Communication About Pain questions, we refer readers to the notice published in the **Federal Register** on Information Collection for the National Implementation of the Hospital CAHPS Survey (83 FR 21296 through 21297). We note that a revised information collection request under OMB control number 0938–0981 will be submitted to OMB based on the update to the HCAHPS Survey in accordance with this final rule with comment period.

As noted above, the removal of the Communication About Pain questions does not change the estimated burden for the Hospital IQR Program under the program's OMB control number 0938–1022. However, we believe that overall cost and burden will change slightly for hospitals and HCAHPS Survey respondents. Under HCAHPS Survey

[232] In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59479 through 59480), we finalized an hourly labor cost to hospitals of $36.58 and specified that this cost included both wage and overhead and fringe benefit costs. The estimate for this duty is available in the Bureau of Labor Statistics report on Occupation Employment and Wages for May 2016, 29–2071 Medical Records and Health Information Technicians at: *https://www.bls.gov/oes/2016/may/oes292071.htm.*

OMB control number 0938–0981, it is estimated that the average cost and hour burdens for hospitals are $4,000 and 1 hour per hospital for HCAHPS data collection activities. Because these estimates include administrative activities and overhead costs, we believe our removal of the Communication About Pain questions from the HCAHPS Survey will not reduce these estimates of hospital burden or will only nominally and temporarily increase the average cost and hour burdens associated with the removal of these questions from the survey, given the need to adjust the survey instrument and instructional materials and, therefore, marginally reduce the burden due to the shortening of the survey instrument.

Under HCAHPS Survey OMB control number 0938–0981, the average time for a respondent to answer the 32 question survey is estimated at 8 minutes, which we estimate to be 0.25 minutes per question (8 minutes/32 questions = 0.25 minutes per question). In addition, under this OMB control number, the number of respondents is estimated at 3,104,200 respondents. In this final rule with comment period, we are finalizing a modified version of our proposal to remove 3 questions, which we estimate would reduce the time burden by 0.75 minutes (0.25 minutes per question × 3 questions), or 0.0125 hours (0.75 minutes/60 minutes) per respondent. We anticipate a total hourly burden reduction for respondents of 38,803 hours (0.0125 hours × 3,104,200 respondents). Further, under OMB control number 0938–0981, the cost of respondent time is based on the average hourly earnings of $26.71 per hour, as reported by the U.S. Bureau of Labor Statistics final January 2018 estimates available on the website at: *https://www.bls.gov/eag/eag.us.htm*.[233] We anticipate a total cost reduction for respondents associated with the proposal to remove the three Communication About Pain questions of $1,036,428 (38,803 total hours × respondent earnings estimate of $26.71 per hour) for the FY 2021 payment determination.

E. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for the FY 2021 Program Year

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503), we proposed to remove two NHSN measures, Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139), from the PCHQR Program beginning with the FY 2021 program year. In section VIII.B.3.b.(2) of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41613), we indicated that we would take final action regarding our proposals to remove the CAUTI and CLABSI measures in a future 2018 final rule. In section XVII. of this final rule with comment period, after consideration of the public comments received, and consideration of the most recent information provided by the CDC, we are not finalizing our proposals to remove the CAUTI and CLABSI measures. We note that this CDC information was not available at the time when we proposed the removal of these measures from the PCHQR Program.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41695) we reconciled the burden estimates associated with the NHSN measures (CLABSI, CAUTI, CDI, HCP, MRSA and Colon and Abdominal Hysterectomy SSI) included in the PCHQR Program, which were formerly accounted for under both the PCHQR Program's estimates OMB control number 0938–1175 and the CDC's estimates under OMB control number 0920–0666. Because the CDC maintains the NHSN system used to collect this data and captures the burden associated with this data collection under its estimates in OMB control number 0920–0666, we removed the duplicative burden estimate from the PCHQR Program's OMB Control Number, 0938–1175. As a result, there is no change in burden under the PCHQR Program associated with not finalizing removal of the CLABSI and CAUTI measures.

In summary, our decisions not to remove the CAUTI and CLABSI measures in the PCHQR Program for FY 2021 program year and subsequent years does not change the information collection estimates for the PCHQR Program. We refer readers to section XIV.B.4 of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41694 through 41695) for more detail on the information collection calculations for the finalized policies in the PCHQR Program.

F. Total Reduction in Burden Hours and in Costs

Below is a chart reflecting the total burden and associated costs for the provisions included in this final rule with comment period.

[233] Average hourly earnings of $26.71 per hour based on the average hourly earnings of all employees on private non-farm payrolls, seasonally adjusted, per the U.S. Bureau of Labor Statistics.

Information Collection Requests	Burden Hours Increase/Decrease (-)*	Cost (+/-)*
Hospital Outpatient Quality Reporting Program	- 681,875	- $24.9 million
Ambulatory Surgical Center Quality Reporting Program	- 62,008	- $2.3 million
Hospital Inpatient Reporting Program – Update to the HCAHPS Survey Measure[1]	- 38,803 hours	- $1 million
PPS-Exempt Center Hospital Quality Reporting Program – Additional Policies[2]	N/A	N/A
Total	- 782,686 hours	- $28.2 million

* Numbers rounded.

[1] We note that the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981.

[2] There is no change in burden associated with not finalizing removal of the CLABSI and CAUTI measures from the PCHQR Program.

XX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXI. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to make updates to the Medicare hospital OPPS rates. It is necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2019. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2017, through and including December 31, 2017, and processed through June 30, 2018, and updated cost report information.

We note that we are finalizing our proposal to control unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at off-campus PBDs at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). The site-specific PFS payment rate for clinic visits furnished in excepted off-campus PBDs is the OPPS rate reduced to the amount paid for clinic visits furnished by nonexcepted off-campus PBDs under the PFS, which is 40 percent of the OPPS rate. We expect that, by removing the payment differential, we will control unnecessary volume increases both in terms of the number of covered outpatient services furnished and the costs of those services. We are implementing this policy with a 2-year phase-in. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these off-campus PBDs were paid the site-specific PFS payment rate for the clinic visit service. In other words, these excepted off-campus PBDs will be paid 70 percent of the OPPS rate for the clinic visit service in CY 2019. In CY 2020, we will complete the transition to paying the PFS-equivalent amount for clinic visits furnished in excepted off-campus PBDs. In other words, these excepted off-campus PBDs will be paid 40 percent of the OPPS rate for the clinic visit service in CY 2020.

This final rule with comment period also is necessary to make updates to the ASC payment rates for CY 2019, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in an ASC in CY 2019. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

For CYs 2019 through 2023, we are finalizing our proposal to update the ASC payment system rates using the hospital market basket update instead of the CPI–U. We believe that this finalized proposal could stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the

migration of services to lower cost settings as clinically appropriate.

B. Overall Impact for Provisions of This Final Rule With Comment Period

We have examined the impacts of this final rule with comment period, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this final rule with comment period contains the impact and other economic analyses for the provisions we are finalizing for CY 2019.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this final rule with comment period. In the CY 2019 OPPS/ASC proposed rule (83 FR 37224), we solicited public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this final rule with comment period, as appropriate.

We estimate that the total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the changes to the OPPS in this final rule with comment period, will be approximately $440 million. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2019, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2019 will be approximately $74.1 billion; approximately $5.8 billion higher than estimated OPPS expenditures in CY 2018. We note that these spending estimates include the final CY 2019 final policy to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus PBDs at a rate that will be 70 percent of the OPPS rate for a clinic visit service. Because the provisions of the OPPS are part of a final rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 62 of this final rule with comment period displays the distributional impact of the CY 2019 changes in OPPS payment to various groups of hospitals and for CMHCs.

As noted in sections V.B.7. and X.C.2. of this final rule with comment period, we are finalizing our proposal for CY 2019 to pay for separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B program at WAC+3 percent instead of WAC+6 percent, if ASP data are unavailable for payment purposes. If WAC data are not available for a drug or biological product, we will continue our policy to pay separately payable drugs and biological products at 95 percent of the AWP. Drugs and biologicals that are acquired under the 340B Program will continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable.

We estimate that the update to the conversion factor and other adjustments (not including the effects of outlier payments, the pass-through payment estimates, the application of the frontier State wage adjustment for CY 2019, and the finalized proposal to control for unnecessary increases in the volume of covered outpatient department services described in section X.B. of this final rule with comment period) will increase total OPPS payments by 1.3 percent in CY 2019. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2018 and CY 2019, considering all budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, the application of the frontier State wage adjustment, and the finalized proposal to control unnecessary increases in the volume of outpatient services as described in section X.B. of this final rule with comment period, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, will increase total estimated OPPS payments by 0.6 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2019 compared to CY 2018, to be approximately $200 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this final rule with comment period. Tables 63 and 64 of this final rule with comment period display the redistributive impact of the CY 2019 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2019 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2019 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1695–FC'' from the list of regulations and notices. The hospital-specific file layout and the

hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 62 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Finalized Proposal To Control for Unnecessary Increases in the Volume of Outpatient Services

In section X.B. of this final rule with comment period, we discuss our CY 2019 finalized proposal to control for unnecessary increases in the volume of outpatient department services by paying for clinic visits furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, we are finalizing our proposal to pay for HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate), with a 2-year transition period. For a discussion of the PFS payment amount for outpatient clinic visits furnished at nonexcepted off-campus PBDs, we refer readers to the CY 2018 PFS final rule with comment period discussion (82 FR 53023 through 53024), as well as the CY 2019 PFS final rule.

To develop an estimated impact of this policy, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 OPPS. We then flagged all claim lines for HCPCS code G0463 that contained modifier ''PO'' because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. Next, we excluded those that were billed as a component of C–APC 8011 (Comprehensive Observation Services) or packaged into another C–APC because in those instances OPPS payment is made for a broader package of services. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate. An estimate of the policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2019 President's budget approximates the estimated decrease in total payment under the OPPS at $380 million, with Medicare OPPS payments decreasing by $300 million and beneficiary copayments decreasing by $80 million in CY 2019. This estimate is utilized for the accounting statement displayed in Table 65 of this final rule with comment period because the impact of this CY 2019 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes in this final rule with comment period. The estimated decrease in payment due to this policy is not as great as in the proposed rule because we are proposing to transition the application of this policy over 2 years.

We note that our estimates may differ from the actual effect of the policy due to offsetting factors, such as changes in provider behavior. We note that, by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of clinic visits provided in the excepted off-campus PBD setting. In the proposed rule, we reminded readers that this estimate could change in this final rule with comment period based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule with comment period. This estimate changed due to the final policy of establishing a 2-year phase-in. As discussed in more detail in section X.B. of the proposed rule, we sought public comment on both our proposed payment policy for clinic visits furnished at off-campus PBDs as well as how to apply methods for controlling overutilization of services more broadly. We refer readers to section X.B. of this final rule with comment period for our discussion of the public comments we received.

c. Estimated Effects of Finalized Proposal To Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of Hospitals

In section X.C. of this final rule with comment period, we discuss the proposal we are finalizing to pay average sales price (ASP) minus 22.5 percent under the PFS for separately payable 340B-acquired drugs furnished by nonexcepted, off-campus PBDs beginning in CY 2019. This is consistent with the payment methodology adopted in CY 2018 for 340B-acquired drugs furnished in hospital departments paid under the OPPS.

To develop an estimated impact of this finalized proposal, we began with CY 2017 outpatient claims data used in ratesetting for the CY 2019 OPPS. We then flagged all claim lines that contained modifier ''PN'' because the presence of this modifier indicates that such claims were billed for services furnished by a nonexcepted off-campus department of a hospital paid under the PFS. We further subset this population by identifying 340B hospitals that billed for status indicator ''K'' drugs or biologicals (that is, nonpass-through, separately payable drugs) because such drugs may have been subject to the 340B discount. We found 117 unique nonexcepted off-campus PBDs associated with 340B hospitals billed for status indicator ''K'' drugs. Their ''K'' billing represents approximately $183 million in Medicare payments (including beneficiary copayments) based on a payment rate of ASP+6 percent. Based on our adjustment, for CY 2019, we estimate that the Medicare Program and beneficiaries will save approximately $49.1 million, under the PFS. This estimate represents an upper bound of potential savings under the PFS for this policy change and does not include adjustments for beneficiary enrollment, case-mix, or potential offsetting behaviors. We noted in the proposed rule that the estimated effect of the proposed policy could change in this final rule with comment period based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule.

d. Estimated Effects of OPPS Changes on Hospitals

Table 62 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all

facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 62, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2019, we are paying CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs), and we are paying hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2019 is 2.9 percent (83 FR 41395). Section 1833(t)(3)(F)(i) of the Act reduces that 2.9 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is 0.8 percentage point for FY 2019 (which is also the MFP adjustment for FY 2019 in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41395)), and sections 1833(t)(3)(F)(ii) and 1833(t)(3)(G)(v) of the Act further reduce the market basket percentage increase by 0.75 percentage point, resulting in the OPD fee schedule increase factor of 1.35 percent. We are using the OPD fee schedule increase factor of 1.35 percent in the calculation of the CY 2019 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2019 estimates in Table 62 of this final rule with comment period.

To illustrate the impact of the CY 2019 changes, our analysis begins with a baseline simulation model that uses the CY 2018 relative payment weights, the FY 2018 final IPPS wage indexes that include reclassifications, and the final CY 2018 conversion factor. Table 62 shows the estimated redistribution of the increase or decrease in payments for CY 2019 over CY 2018 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2018 and CY 2019 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 1.35 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the finalized off-campus PBD clinic visits payment policy (Column 5), and the estimated impact taking into account all payments for CY 2019 relative to all payments for CY 2018, including the impact of changes in estimated outlier payments, the frontier State wage adjustment, and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2019. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2019 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2018 and CY 2019 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2019 will increase Medicare OPPS payments by an estimated 0.6 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 0.6 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 62 shows the total number of facilities (3,840), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2017 hospital outpatient and CMHC claims data to model CY 2018 and CY 2019 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2018 or CY 2019 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,727), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 46 CMHCs at the bottom of the impact table and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from an increase of 0.4 percent to a decrease of 0.1 percent, depending on the number of beds. Rural hospitals will experience

an increase of 0.1 percent, with the impact ranging from a decrease of 0.3 percent to an increase of 0.4 percent, depending on the number of beds. Major teaching hospitals will experience no change.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2019 IPPS post-reclassification wage indexes; the rural adjustment; and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2018 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis. This column excludes the effects of the frontier State wage index adjustment, which is not budget neutral and is included in Column 6. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2019, as described in section II.E. of this final rule with comment period. We also did not model a budget neutrality adjustment for the cancer hospital payment adjustment because we are using a payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2019 of 0.89, which is the same ratio that was reported for the CY 2018 OPPS/ASC final rule with comment period (82 FR 59266). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we are applying in section II.F. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2019 scaled weights and a CY 2018 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2018 and CY 2019. The FY 2019 wage policy results in modest redistributions.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 1.35 percent. Overall, these changes will increase payments to urban hospitals by 1.4 percent and to rural hospitals by 1.3 percent. Urban hospitals will receive an increase in line with the 1.4 percent overall increase for all facilities after the update is applied to the budget neutrality adjustments. The increase for classes of rural hospitals will be more variable with sole community hospitals receiving a 1.1 percent increase and other rural hospitals receiving an increase of 1.6 percent.

Column 5: Off-Campus PBD Visits Payment Policy

Column 5 displays the estimated effect of our finalized CY 2019 volume control method to pay for clinic visit HCPCS code G0463 ((Hospital outpatient clinic visit for assessment and management of a patient) when billed with modifier ''PO'' by an excepted off-campus PBD at a rate that will be 70 percent of the OPPS rate for a clinic visit service for CY 2019. We note that the numbers provided in this column isolate the estimated effect of this policy adjustment relative to the numerator of Column 4. Therefore, the numbers reported in Column 5 show how much of the difference between the estimates in Column 4 and the estimates in Column 6 are a result of the finalized off-campus PBD visits policy.

Column 6: All Changes for CY 2019

Column 6 depicts the full impact of the CY 2019 policies on each hospital group by including the effect of all changes for CY 2019 and comparing them to all estimated payments in CY 2018. Column 6 shows the combined budget neutral effects of Columns 2 through 3; the OPD fee schedule increase; the effect of the finalized off-campus PBD visits policy, the impact of the frontier State wage index adjustment; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIII. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2018 update (and assumed, for modeling purposes, to be the same number for CY 2019), we included 72 hospitals in our model because they had both CY 2017 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2019 will increase payments to all facilities by 0.6 percent for CY 2019. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2018 and the relative payment weights for CY 2019. We used the final conversion factor for CY 2018 of $78.636 and the final CY 2019 conversion factor of $79.490 discussed in section II.B. of this final rule with comment period.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41722) of 4.3 percent (1.04338) to increase individual costs on the CY 2017 claims, and we used the most recent overall CCR in the October 2018 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2018. Using the CY 2017 claims and a 4.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2018, using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,150, will be approximately 1.01 percent of total payments. The estimated current outlier payments of 1.01 percent are incorporated in the comparison in Column 6. We used the same set of claims and a charge inflation factor of 8.9 percent (1.08864) and the CCRs in the October 2018 OPSF, with an adjustment of 0.981397, to reflect relative changes in cost and charge inflation between CY 2017 and CY 2019, to model the CY 2019 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $4,825. The charge inflation and CCR inflation factors are discussed in detail in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41722).

Overall, we estimate that facilities will experience an increase of 0.6 percent under this final rule with comment period in CY 2019 relative to total spending in CY 2018. This projected increase (shown in Column 6) of Table 62 reflects the 1.35 percent OPD fee schedule increase factor, minus 0.6 percent for the off-campus PBD visits policy, minus 0.10 percent for the change in the pass-through payment estimate between CY 2018 and CY 2019, plus a decrease of 0.01 percent for the difference in estimated outlier payments

between CY 2018 (1.01 percent) and CY 2019 (1.00 percent). We estimate that the combined effect of all changes for CY 2019 will increase payments to urban hospitals by 0.7 percent. Overall, we estimate that rural hospitals will experience a 0.5 percent increase as a result of the combined effects of all the changes for CY 2019.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 0.4 percent for major teaching hospitals and an increase of 0.9 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 0.5 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 0.6 percent, proprietary hospitals will experience an increase of 1.0 percent, and governmental hospitals will experience an increase of 0.5 percent.

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TABLE 62.—ESTIMATED IMPACT OF THE CY 2019 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
ALL FACILITIES *		3,840	0.0	0.0	1.3	-0.6	0.6
ALL HOSPITALS		3,727	0.0	0.0	1.4	-0.6	0.6
(excludes hospitals permanently held harmless and CMHCs)							
URBAN HOSPITALS		2,938	0.0	0.0	1.4	-0.6	0.7
	LARGE URBAN	1,542	0.1	-0.1	1.3	-0.5	0.7
	(GT 1 MILL.)						
	OTHER URBAN	1,396	0.0	0.1	1.5	-0.7	0.6
	(LE 1 MILL.)						
RURAL HOSPITALS		789	0.1	-0.2	1.3	-0.6	0.5
	SOLE COMMUNITY	370	-0.1	-0.2	1.1	-0.7	0.2
	OTHER RURAL	419	0.4	-0.1	1.6	-0.6	0.9
BEDS (URBAN)							
	0 - 99 BEDS	1,018	0.4	-0.1	1.6	-0.4	1.1
	100-199 BEDS	846	0.1	-0.1	1.4	-0.5	0.7
	200-299 BEDS	468	0.0	0.1	1.5	-0.5	0.9
	300-499 BEDS	390	-0.1	0.0	1.3	-0.6	0.5
	500 + BEDS	216	0.0	0.1	1.4	-0.8	0.5
BEDS (RURAL)							
	0 - 49 BEDS	328	0.4	0.0	1.7	-0.2	1.3
	50- 100 BEDS	288	0.2	-0.1	1.4	-0.8	0.5
	101- 149 BEDS	89	0.2	-0.2	1.3	-0.5	0.7
	150- 199 BEDS	47	0.1	-0.4	1.1	-1.1	-0.1
	200 + BEDS	37	-0.3	-0.3	0.7	-0.5	0.1
REGION (URBAN)							
	NEW ENGLAND	143	0.2	1.7	3.3	-1.0	2.1
	MIDDLE ATLANTIC	336	0.0	-0.2	1.1	-0.4	0.6
	SOUTH ATLANTIC	469	0.0	-0.4	1.0	-0.5	0.4

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	EAST NORTH CENT.	469	0.0	-0.3	1.0	-0.8	0.1
	EAST SOUTH CENT.	178	0.0	-0.2	1.2	-0.2	0.9
	WEST NORTH CENT.	182	-0.2	-0.2	1.0	-0.6	0.1
	WEST SOUTH CENT.	517	0.1	0.0	1.4	-0.5	0.8
	MOUNTAIN	214	0.0	0.2	1.5	-0.6	0.8
	PACIFIC	384	0.1	0.5	1.9	-0.6	1.1
	PUERTO RICO	46	-0.6	-1.2	-0.4	0.0	-0.4
REGION (RURAL)							
	NEW ENGLAND	21	-0.1	-0.7	0.5	-2.0	-1.6
	MIDDLE ATLANTIC	54	0.2	0.1	1.6	-1.0	0.5
	SOUTH ATLANTIC	122	0.1	-0.2	1.3	-0.2	1.0
	EAST NORTH CENT.	120	0.3	-0.2	1.5	-0.8	0.5
	EAST SOUTH CENT.	152	0.1	0.1	1.5	-0.3	1.1
	WEST NORTH CENT.	95	-0.2	-0.2	1.0	-0.8	-0.2
	WEST SOUTH CENT.	151	0.5	0.2	2.0	-0.3	1.6
	MOUNTAIN	51	-0.2	-0.6	0.5	-0.2	0.9
	PACIFIC	23	0.1	-0.4	1.1	-1.0	-0.1
TEACHING STATUS							
	NON-TEACHING	2,599	0.1	-0.1	1.4	-0.4	0.9
	MINOR	776	0.0	0.0	1.3	-0.6	0.5
	MAJOR	352	0.0	0.1	1.5	-0.9	0.4
DSH PATIENT PERCENT							
	0	11	-0.8	-0.5	0.1	0.0	0.2
	GT 0 - 0.10	265	0.1	-0.2	1.3	-0.4	0.8
	0.10 - 0.16	241	0.0	-0.1	1.2	-0.4	0.7
	0.16 - 0.23	575	-0.1	-0.2	1.0	-0.6	0.3
	0.23 - 0.35	1,113	0.1	0.0	1.4	-0.7	0.6
	GE 0.35	953	0.1	0.1	1.6	-0.6	0.8

		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**Off-Campus Provider-Based Department Visits Policy**	**All Changes**
	DSH NOT AVAILABLE **	569	2.5	0.0	3.9	-0.3	3.4
URBAN TEACHING/DSH							
	TEACHING & DSH	1,013	0.0	0.1	1.4	-0.7	0.5
	NO TEACHING/DSH	1,369	0.1	0.0	1.4	-0.4	0.9
	NO TEACHING/NO DSH	10	1.2	-1.0	1.5	0.0	1.3
	DSH NOT AVAILABLE**	545	2.5	0.0	3.9	-0.3	3.4
TYPE OF OWNERSHIP							
	VOLUNTARY	1,977	0.0	0.0	1.4	-0.7	0.6
	PROPRIETARY	1,281	0.1	0.0	1.4	-0.2	1.0
	GOVERNMENT	469	0.0	0.1	1.4	-0.7	0.5
CMHCs		46	-16.8	0.7	-15.0	0.0	-15.1

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2019 OPPS policies and compares those to the CY 2018 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2019 hospital inpatient wage index. The rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1 because in CY 2019 the target payment-to-cost ratio is the same as it was in CY 2018 (0.88).

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 1.35 percent OPD fee schedule update factor (2.9 percent reduced by 0.8 percentage point for the productivity adjustment and further reduced by 0.75 percentage point as required by law).

Column (5) shows the additional impact of the policy to pay clinic visits for nonexcepted providers under the otherwise applicable payment system. We note that we are applying a 2-year phase-in so the amount of the reduction will be 50 percent of the difference in CY 2019 (or payment at 70 percent of the OPPS rate).

Column (6) shows the additional adjustments to the conversion factor resulting from the frontier adjustment, a change in the pass-through estimate, and adding estimated outlier payments.

* These 3,840 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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e. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 62 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2018, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2017 claims used for ratesetting in this final rule with comment period. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 15.1 percent decrease in payments from CY 2018 (shown in Column 6). We note that this includes the trimming methodology described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the FY 2019 wage index values will result in an increase of 0.7 percent to CMHCs. Column 4 shows that combining this OPD fee schedule increase factor, along with changes in APC policy for CY 2019 and the FY 2019 wage index updates, will result in an estimated decrease of 15.0 percent. Column 5 shows that the off-campus PBD clinic visits payment policy has no effect on CMHCs. Column 6 shows that adding the changes in outlier and pass-through payments will result in a total 15.1 percent decrease in payment for CMHCs. This reflects all changes to CMHCs for CY 2019.

f. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion on the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage will be 18.5 percent for all services paid under the OPPS in CY 2019. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the CY 2019 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule with comment period. The aggregate coinsurance percentage reflects changes that we have made for the CY 2019 OPPS. Total estimated copayments over total estimated payments results in 18.6 percent. Under the C–APC payment methodology, the copayment is based on the claim level for the C–APC rather than the service line level. Because outpatient copayment is capped at the inpatient deductible, this can lead to an aggregate cost-sharing below 20 percent.

g. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XII. of this final rule with comment period. We do not anticipate that any types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the changes in this final rule with comment period. However, we are interested in exploring how these Medicare changes may affect others in the health care marketplace.

h. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $440 million in program payments for OPPS services furnished in CY 2019. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule with comment period will increase these Medicaid beneficiary payments by approximately $35 million in CY 2019. Currently, there are approximately 10 million dual-eligible beneficiaries, which represents approximately one third of Part B FFS beneficiaries. The impact on Medicaid was determined by taking one-third of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $35 million Medicaid increase, approximately $20 million would be from the Federal Government and $15 million would be from State government.

i. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

• Alternatives Considered for the Method to Control for Unnecessary Increases in the Volume of Outpatient Services

We refer readers to section X.B. of this final rule with comment period for a discussion of our policy to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For 2019, we proposed to apply a PFS-equivalent payment rate for this service. However, after consideration of public comments received, we are phasing in the application of the reduction in payment for HCPCS code G0463 in this setting over 2 years. In CY 2019, the payment reduction will be transitioned by applying 50 percent of the total reduction in payment that would apply if these departments were paid the site-specific PFS rate for the clinic visit service. We also considered, but did not finalize, fully applying this payment reduction in CY 2019. Had we done so, total Medicare and beneficiary copayments in CY 2019 would have decreased by $750 million, compared to the decrease of $380 million as a result of the phase-in.

• Alternatives Considered for the Methodology for Assigning Skin Substitutes to High or Low Cost Groups

We refer readers to section V.B.1.d. of this final rule with comment period for a discussion of our policy to assign any skin substitute product that was assigned to the high cost group in CY 2018 to the high cost group in CY 2019, regardless of whether the product's mean unit cost (MUC) or the product's per day cost (PDC) exceeds or falls below the overall CY 2019 MUC or PDC threshold. We will continue to assign products that exceed either the overall CY 2019 MUC or PDC threshold to the high cost group. We also considered, but did not propose, reinstating our methodology from CY 2017 and assigning skin substitutes to the high cost group based on whether an individual product's MUC or PDC exceeded the overall CY 2019 MUC or PDC threshold based on calculations done for either the proposed rule or the final rule with comment period.

• Alternatives Considered for the Methodology for Payment for Non-Opioid Pain Management Treatments

We refer readers to sections II.A.3.b. and XII.D.3. of the proposed rule and this final rule with comment period for a discussion of our change in the packaging policy for certain drugs when administered in the ASC setting and policy provide separate payment for non-opioid pain management drugs that function as a supply when used in a surgical procedure when the procedure is performed in an ASC. In those sections of the proposed rule, we also solicited comments on whether we should pay separately for other non-opioid treatments for pain under the OPPS and the ASC payment system. We discuss the comments we received in those sections of this final rule with comment period. In the proposed rule, we also considered and solicited comments on an alternative policy that would use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish an incentive payment for non-opioid alternatives that would apply to drugs and devices under

the OPPS that are not currently separately paid, are supported by evidence that demonstrates such drugs and devices are effective at treating acute or chronic pain, and would result in decreased use of prescription opioid drugs and any associated opioid addiction, when furnished in the outpatient setting. We discuss the comments we received in those sections of this final rule with comment period.

2. Estimated Effects of CY 2019 ASC Payment System Changes in This Final Rule With Comment Period

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XII. of this final rule with comment period, we are setting the CY 2019 ASC relative payment weights by scaling the CY 2019 OPPS relative payment weights by the ASC scalar of 0.8792. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 63 and 64 below.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which will be the hospital market basket for CY 2019) after application of any quality reporting reduction be reduced by a productivity adjustment. The Affordable Care Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2019 payment determinations will be based on the application of a 2.0 percentage point reduction to the annual update factor, which will be the hospital market basket for CY 2019. We calculated the CY 2019 ASC conversion factor by adjusting the CY 2018 ASC conversion factor by 1.0004 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2018 and CY 2019 and by applying the CY 2019 MFP-adjusted hospital market basket update factor of 2.1 percent (hospital market basket update of 2.9 percent minus a projected productivity adjustment of 0.8 percentage point). The CY 2019 ASC conversion factor is $46.555 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2019 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2017 and CY 2019 with precision. We believe the net effect on Medicare expenditures resulting from the CY 2019 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2019 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2019 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2017 claims data. Table 63 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2018 payments to estimated CY 2019 payments, and Table 64 shows a comparison of estimated CY 2018 payments to estimated CY 2019 payments for procedures that we estimate will receive the most Medicare payment in CY 2018.

In Table 63, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 63.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—Estimated CY 2018 ASC Payments were calculated using CY 2017 ASC utilization data (the most recent full year of ASC utilization) and CY 2018 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2018 ASC payments.
- Column 3—Estimated CY 2019 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that are attributable to updates to ASC payment rates for CY 2019 compared to CY 2018.

As shown in Table 63, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC payment rates for CY 2019 will result in a 1-percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 3-percent increase in aggregate payment amounts for nervous system procedures, 3-percent increase in aggregate payment amounts for digestive system procedures, a 3-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 1-percent increase in aggregate payment amounts for genitourinary system procedures, and a 1-percent decrease in aggregate payment amounts for integumentary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.1 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.1 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services

increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 1-percent decrease in aggregate eye and ocular adnexa procedure payments due to a reduction in hospital reported costs for the primary payment grouping for this category under the OPPS. This lowers the payment weights for eye and ocular adnexa procedure payments and, overall, offsets the 2.1 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 64 provided later in this section.

Also displayed in Table 63 is a separate estimate of Medicare ASC payments for the group of separately payable covered ancillary items and services. The payment estimates for the covered surgical procedures include the costs of packaged ancillary items and services. We estimate that aggregate payments for these items and services will increase by 79 percent for CY 2019. This is largely attributed to the introduction of utilization data for HCPCS code C9447 (Inj, phenylephrine ketorolac), Omidria®, and HCPCS code Q4172 (Puraply or puraply am), a high-cost skin substitute.

TABLE 63.—ESTIMATED IMPACT OF THE CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2019 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2018 ASC Payments (in Millions) (2)	Estimated CY 2019 Percent Change (3)
Total	$4,772	2
Eye and ocular adnexa	$1,737	-1
Nervous system	$993	3
Digestive system	$873	3
Musculoskeletal system	$574	3
Genitourinary system	$188	1
Integumentary system	$145	-1
Ancillary items and services	$64	79

Table 64 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2019. The table displays 30 of the procedures receiving the greatest estimated CY 2018 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2018 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2018 ASC Payments were calculated using CY 2017 ASC utilization (the most recent full year of ASC utilization) and the CY 2018 ASC payment rates. The estimated CY 2018 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2019 Percent Change reflects the percent differences between the estimated ASC payment for CY 2018 and the estimated payment for CY 2019 based on the update.

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TABLE 64.—ESTIMATED IMPACT OF THE CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2018 ASC Payment (in millions) (3)	Estimated CY 2019 Percent Change (4)
66984	Cataract surg w/iol 1 stage	$1,206	-2
45380	Colonoscopy and biopsy	$228	4
63685	Insrt/redo spine n generator	$221	-1
43239	Egd biopsy single/multiple	$180	1
63650	Implant neuroelectrodes	$166	-3
45385	Colonoscopy w/lesion removal	$156	4
64483	Inj foramen epidural l/s	$101	13
0191T	Insert ant segment drain int	$96	4
66982	Cataract surgery complex	$89	-2
64635	Destroy lumb/sac facet jnt	$75	-1
66821	After cataract laser surgery	$69	1
29827	Arthroscop rotator cuff repr	$65	1
64493	Inj paravert f jnt l/s 1 lev	$63	13
62323	Njx interlaminar lmbr/sac	$53	9
64590	Insrt/redo pn/gastr stimul	$51	3
G0105	Colorectal scrn; hi risk ind	$47	4
G0121	Colon ca scrn not hi rsk ind	$42	4
45378	Diagnostic colonoscopy	$41	4
64721	Carpal tunnel surgery	$34	-1
15823	Revision of upper eyelid	$33	-2
29881	Knee arthroscopy/surgery	$29	-2
C9740	Cysto impl 4 or more	$28	2
64561	Implant neuroelectrodes	$26	-2
67042	Vit for macular hole	$26	0
29880	Knee arthroscopy/surgery	$25	-2
26055	Incise finger tendon sheath	$25	-4
28285	Repair of hammertoe	$24	-2
63655	Implant neuroelectrodes	$24	5
52000	Cystoscopy	$23	-2
G0260	Inj for sacroiliac jt anesth	$22	9

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c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2019 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures we are adding to the ASC list of covered surgical procedures, the existing covered surgical procedures we reviewed as safe to perform in an ASC, and for those surgical procedures we are designating as office-based for CY 2019. For example, using 2017 utilization data and CY 2019 OPPS and ASC payment rates, we estimate that if 5 percent of

cardiac catheterization procedures migrate from the hospital outpatient setting to the ASC setting as a result of this policy, Medicare payments will be reduced by approximately $36 million in CY 2019 and total beneficiary copayments will decline by approximately $14 million in CY 2019. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC rate setting methodology or at the nonfacility practice expense based amount payable under the PFS. Because of this fact, we do not believe that the increase in ASC payment rates that will result from this policy will cause any significant migration of services from the physician office setting to the ASC setting. For those additional procedures that we are designating as office-based in CY 2019, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

d. Alternative ASC Payment Policies Considered

Alternatives to the ASC changes we are making and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

• Alternatives Considered for the CY 2019 ASC Rate Update

As discussed in section XII. of this final rule with comment period, for CY 2019 through CY 2023 (5 years total), in response to stakeholder concerns regarding the application of CPI–U to update ASC payment rates, we are updating ASC payment rates using the hospital market basket and revising our regulations under 42 CFR 416.171(a), which address the annual update to the ASC conversion factor, to reflect this policy.

As an alternative proposal, we considered whether to continue applying the CPI–U as the update factor. If we were to update ASC payment rates for CY 2019 with an update factor based on CPI–U, the update would have been 1.8 percent (the 2.6 percentage point CPI–U less the 0.8 percentage point MFP adjustment). This update factor would have resulted in increased payments to ASCs in CY 2019 of approximately $60 million, compared to the increased payments to ASCs in CY 2019 of approximately $80 million as a result of the 2.1 percent update based on the hospital market basket.

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/circulars_a004_a-4#a*),we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period. The first accounting statement, Table 65 below, illustrates the classification of expenditures for the CY 2019 estimated hospital OPPS incurred benefit impacts associated with the CY 2019 OPD fee schedule increase. This $440 million in additional Medicare spending estimate includes the $740 million in additional Medicare spending associated with updating the CY 2018 OPPS payment rates by the hospital market basket update for CY 2019, offset by the $300 million in Medicare savings associated with the finalized policy to pay for clinic visits furnished at off-campus PBDs at a PFS-equivalent rate. In addition, we estimate that OPPS changes in this final rule with comment period will increase copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries by approximately $35 million in CY 2019. The second accounting statement, Table 66 below illustrates the classification of expenditures associated with the 2.1 percent CY 2019 update to the ASC payment system, based on the provisions of this final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

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TABLE 65.—ACCOUNTING STATEMENT: CY 2019 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2018 TO CY 2019 ASSOCIATED WITH THE CY 2019 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$440 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$440 million

TABLE 66.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2018 TO CY 2019 AS A RESULT OF THE CY 2019 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$80 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$80 million

TABLE 67.—ESTIMATED COSTS, COST SAVINGS, AND BENEFITS

CATEGORY	Costs	Cost Savings
ICR Burden Savings		$28.2 million*
Regulatory Familiarization	$2.6 million*	

*The annual estimates are in 2017 year dollars.

** Regulatory familiarization costs occur upfront only.

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4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital OQR Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the approximately 3,300 hospitals that met eligibility requirements for the CY 2018 payment determination, we determined that 36 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. Many of these hospitals (18 of the 36), chose not to participate in the Hospital OQR Program for the CY 2018 payment determination. In the proposed rule, we did not propose to add any quality measures to the Hospital OQR Program measure set for the CY 2020 or CY 2021 payment determinations, and, in this final rule with comment period we are finalizing our proposals to remove eight measures from the program measure set; we are not finalizing our proposals to remove two measures, as discussed in section XIII.B.4.b. of this final rule with comment period. We do not believe that the finalized policies will increase the number of hospitals that do not receive a full annual payment update for the CY 2020 or CY 2021 payment determinations.

In section XIII.B.4.b. of this final rule with comment period, we are finalizing our proposals to remove a total of eight measures. Specifically, beginning with the CY 2020 payment determination, we are finalizing the removal of: (1) OP–27: Influenza Vaccination Coverage Among Healthcare Personnel; and beginning with the CY 2021 payment determination, we are removing: (2) OP–5: Median Time to ECG; (3) OP–9: Mammography Follow-up Rates; (4) OP–11: Thorax CT Use of Contrast Material; (5) OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; (6) OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT; (7) OP–17: Tracking Clinical Results between Visits; and (8) OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. However, we are not finalizing our proposals to remove two measures: OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery for the CY 2021 payment determination and subsequent years. Therefore, we are revising the estimated burden changes found in the CY 2019 OPPS/ASC proposed rule (83 FR 37234 through 32736). The reduction in burden associated with our finalized policies is discussed below.

In section XIII.B.4.a. of this final rule with comment period, beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, we are updating one removal factor and adding one removal factor. We are also codifying our measure removal policies and factors at 42 CFR 419.46(h) effective upon finalization of this CY 2019 OPPS/ASC final rule with comment period and for subsequent years. In addition, in section XIII.D.2. of this final rule with comment period, we are updating the frequency with which we will release Hospital Outpatient Quality Reporting Specifications Manuals, such that instead of releasing the full manual once or twice each year, as proposed, we will release the Specifications Manuals once every 12 months and release addenda as necessary, beginning with CY 2019 and for subsequent years. In section XIII.C.2. of this final rule with comment period, beginning with the CY 2020 payment determination, we are removing the Notice of Participation (NOP) form as a requirement for the Hospital OQR Program and updating 42 CFR 419.46(a)(3) to reflect this policy. Finally, in section XIII.D.4.b. of this final rule with comment period, we are changing the data reporting period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination. As discussed below, we do not expect these policies to affect our burden estimates. However, as further explained in section XIX.B. of this final rule with comment period, we believe that there will be an overall decrease in the estimated information collection burden for hospitals due to the other finalized policies. We refer readers to section XIX.B. of this final rule with comment

period for a summary of our information collection burden estimate calculations. The effects of these proposals are discussed in more detail further below.

b. Estimated Effects of Hospital OQR Program Beginning With the Effective Date of This CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIII.B.4.a. of this final rule with comment period, we are: (1) Updating measure removal Factor 7; (2) adding one new removal factor; and (3) codifying our removal factors policy at 42 CFR 419.46(h). We do not expect a change in the information collection burden or other costs experienced by hospitals because these changes do not affect Hospital OQR Program participation requirements or data reporting requirements.

c. Update to the Frequency of Releasing the Hospital Outpatient Quality Reporting Specifications Manual Beginning With CY 2019 and for Subsequent Years

In section XIII.D.2. of this final rule with comment period, we are finalizing with modification our proposal to update the frequency with which we will release a Hospital Outpatient Quality Reporting Specifications Manual such that instead of releasing a full manual once or twice each year, as proposed, we will release the Specifications Manuals once every 12 months and release addenda as necessary, beginning with CY 2019 and for subsequent years. We anticipate that this change will reduce hospital confusion, as potentially releasing fewer manuals per year reduces the need to review updates as frequently as was previously necessary. However, because this change does not affect Hospital OQR Program participation requirements or data reporting requirements, we do not estimate a change in our calculation of the information collection burden experienced by hospitals.

d. Estimated Effects of Hospital OQR Program Finalized Proposals for the CY 2020 Payment Determination and Subsequent Years

(1) Removal of the Notice of Participation (NOP) Form Requirement

In section XIII.C.2. of this final rule with comment period, beginning with the CY 2020 payment determination, we are removing the NOP form as a requirement. As a result, to be a participant in the Hospital OQR Program, hospitals will need to: (1) Register on the QualityNet website, (2) identify and register a QualityNet security administrator, and (3) submit data. In addition, we are updating 42 CFR 419.46(a) to reflect these policies. We believe that the finalized policy to remove the NOP will reduce administrative burden experienced by hospitals by only a nominal amount. As a result, this finalized policy does not influence our information collection burden estimates. We refer readers to section XIX.B. of this final rule with comment period, where our burden calculations for the Hospital OQR Program are discussed in detail. In addition, we anticipate that this finalized proposal will reduce the possibility of hospitals failing to meet Hospital OQR Program requirements due to a failure to submit the NOP.

(2) Extension of the Reporting Period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIII.D.4.b. of this final rule with comment period, we are increasing the data reporting period for OP–32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination. We expect this policy to increase the reliability of OP–32 data allowing better information to be publicly reported. However, the policy does not change our data reporting requirements, such that hospitals will be required to continue reporting claims data that are used to calculate this measure. Therefore, we do not expect a change in the information collection burden experienced by hospitals.

(3) Removal of OP–27 for the CY 2020 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are removing OP–27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) beginning with the CY 2020 payment determination and for subsequent years. The burden associated with OP–27, a NHSN measure, is accounted for under a separate Paperwork Reduction Act Package, OMB control number 0920–0666. Because burden associated with submitting data for this measure is captured under a separate OMB control number, we are not providing an estimate of the information collection burden associated with this measure for the Hospital OQR Program. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

e. Estimated Effects of Hospital OQR Program Proposals for the CY 2021 Payment Determination and Subsequent Years

(1) Removal of Chart-Abstracted Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are removing OP–5: Median Time to ECG, a chart-abstracted measure, for the CY 2021 payment determination and subsequent years. We believe that the removal of this chart-abstracted measure for the CY 2021 payment determination will reduce collection of information burden by 151,800 hours and $5.6 million (151,800 hours × $36.58), as discussed in section XIX.B. of this final rule with comment period. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

(2) Removal of Measures Submitted via a Web-Based Tool for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, while we proposed to remove five measures, we are only finalizing the removal of three measures submitted via a web-based tool beginning with the CY 2021 payment determination and for subsequent years: OP–12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data; OP–17: Tracking Clinical Results between Visits; and OP–30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. We are not finalizing the removal of OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients; and OP–31: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. Therefore, we are revising the estimated burden changes found in the CY 2019 OPPS/ASC proposed rule (83 FR 37234 through 32736). As discussed in section XIX.B. of this final rule with comment period, we anticipate a burden

reduction of 530,075 hours and $19.4 million associated with the removal of OP–12, OP–17, and OP–30 for the CY 2021 payment determination. Aside from burden associated with information collection however, we also anticipate that hospitals will experience a general burden and cost reduction associated with these measure removals stemming from no longer having to implement, review, track, and maintain program requirements associated with these measures.

(3) Removal of Claims-Based Measures for the CY 2021 Payment Determination and Subsequent Years

In section XIII.B.4.b. of this final rule with comment period, we are removing three claims-based measures beginning with the CY 2021 payment determination: OP–9: Mammography Follow-up Rates; OP–11: Thorax CT Use of Contrast Material; and OP–14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT. These claims-based measures are calculated using only data already reported to the Medicare program for payment purposes, therefore, we do not believe removing these measures will affect the information collection burden on hospitals. Nonetheless, we anticipate that hospitals will experience a general burden reduction associated with these proposals stemming from no longer having to review and track various associated program requirements.

In total for the CY 2021 payment determination, we expect information collection burden will be reduced by 151,800 hours due to our removal of one chart-abstracted measure, and 530,075 hours due to our removal of three measures submitted via a web-based tool. In total, we estimate an information collection burden reduction of 681,875 hours (151,800 hours for the removal of one chart-abstracted measure + 530,075 hours for the removal of three web-based measures) and $24.9 million (681,875 hours × $36.58) for the CY 2021 payment determination.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XIV. of this final rule with comment period, we discuss our adopted policies affecting the ASCQR Program. For the CY 2018 payment determination, of the 6,683 ASCs that met eligibility requirements for the ASCQR Program, 233 ASCs did not meet the requirements to receive the full annual payment update. We note that, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79874), we used the CY 2016 payment determination numbers as a baseline, and estimated that approximately 200 ASCs will not receive the full annual payment update in CY 2019 due to failure to meet the ASCQR Program requirements (CY 2017 and CY 2018 payment determination information were not yet available). In the proposed rule, we did not propose to add any new quality measures to the ASCQR Program measure set for the CY 2020 payment determination and subsequent determinations, and we do not believe that the other measures we previously adopted will cause any additional ASCs to fail to meet the ASCQR Program requirements. Therefore, we do not believe that our finalized proposals will increase the number of ASCs that do not receive a full annual payment update for the CY 2020 payment determination. Below we discuss only the effects that will result from the newly finalized provisions in this final rule with comment period.

In section XIV.B.3.c. of this final rule with comment period, we are removing one measure beginning with the CY 2020 payment determination (ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel) and removing one measure beginning with the CY 2021 payment determination (ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use). We expect these measure removals will reduce the overall burden of reporting data for the ASCQR Program, as discussed further below. In section XIV.B.3.c. of this final rule with comment period, we are not finalizing our proposals to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. In addition, we are not finalizing our proposals to remove ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All-Cause Hospital Transfer/Admission, but are instead retaining the measures in the ASCQR Program and suspending their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the measures. Therefore, we are revising the estimated burden changes found in the CY 2019 OPPS/ASC proposed rule (83 FR 37236 through 32737).

In sections XIV.B.3.b. and XIV.D.4.b. of this final rule with comment period, beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, we are finalizing our proposals to: (1) Remove one measure removal factor; (2) adding two new measure removal factors, and (3) update 42 CFR 416.320(c) to better reflect our measure removal policies; we are also: (4) Extend the reporting period for ASC–12: Facility Seven-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy from 1 to 3 years beginning with the CY 2020 payment determination. As discussed below, we do not expect these policies will affect our burden estimates. However, as further explained in section XIX.C. of this final rule with comment period, we believe that there will be an overall decrease in the estimated information collection burden for ASCs due to the other finalized policies. We refer readers to section XIX.C. of this final rule with comment period for a summary of our information collection burden estimate calculations. The effects of these policies are discussed in more detail below.

b. Estimated Effects of ASCQR Program Newly Finalized Policies Beginning With the Effective Date of This CY 2019 OPPS/ASC Final Rule With Comment Period

In section XIV.B.3.a. of this final rule with comment period, we are, beginning with the effective date of this CY 2019 OPPS/ASC final rule with comment period, removing one measure removal factor, adding two new measure removal factors, and updating 42 CFR 416.320(c) to better reflect our measure removal policies for the ASCQR Program. Because these changes do not affect ASCQR Program participation requirements or data reporting requirements, we do not expect these newly finalized policies to change the information collection burden or other costs experienced by ASCs.

c. Estimated Effects of ASCQR Program Newly Finalized Policies for the CY 2020 Payment Determination and Subsequent Years

(1) Extension of the Reporting Period for ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

In section XIV.D.4.b. of this final rule with comment period, we are extending the data reporting period for ASC–12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years beginning with the CY 2020 payment determination. We expect this newly finalized policy to increase the

reliability of ASC–12 data allowing better information to be publicly reported. However, the policy does not change our data reporting requirements, because ASC–12 is a claims-based measure that is calculated based on claims data that facilities already submit to CMS. Therefore, we do not expect a change in the information collection burden or other costs experienced by ASCs.

(2) Removal of ASC–8 for the CY 2020 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this final rule with comment period, we are removing one measure from the ASCQR Program measure set beginning with the CY 2020 payment determination, ASC–8: Influenza Vaccination Coverage Among Healthcare Personnel. As discussed in section XIX.C.3.b. of this final rule with comment period, the information collection burden associated with ASC–8, a NHSN measure, is accounted for under a separate information collection request, OMB control number 0920–0666. As such, we are not providing an estimate of the information collection burden associated with this measure under the ASCQR Program control number. Aside from burden associated with information collection however, we anticipate that facilities will experience a general burden and cost reduction associated with this proposal stemming from no longer having to review and track program requirements associated with this measure.

d. Estimated Effects of ASCQR Program Newly Finalized Policies for the CY 2021 Payment Determination and Subsequent Years: Removal of One Chart-Abstracted Measure for the CY 2021 Payment Determination and Subsequent Years

In section XIV.B.3.c. of this final rule with comment period, we proposed to remove seven measures; we are finalizing the removal of only one measure from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. In section XIV.B.3.c. of this final rule with comment period we are not finalizing our proposal to remove ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. In addition, we are not finalizing our proposals to remove ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and ASC–4: All Cause Hospital Transfer/Admission, but are instead retaining the measures in the ASCQR Program and suspending their data collection beginning with the CY 2019 reporting period/CY 2021 payment determination until further action in rulemaking with the goal of updating the measures. Therefore, we are revising the estimated burden changes found in the CY 2019 OPPS/ASC proposed rule (83 FR 37222).

While we proposed to remove three chart-abstracted measures, in section XIV.B.3.c. of this final rule with comment period, we are finalizing the removal of only one chart-abstracted measure from the ASCQR Program measure set beginning with the CY 2021 payment determination: ASC–10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use. We are not finalizing the removal of ASC–9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients and ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery. As discussed in section XIX.C.4.b. of this final rule with comment period, we believe the removal of ASC–10 will result in a burden reduction for ASCs. For ASC–10, we estimate the total annualized burden reduction to be 62,008 hours and $2,268,244 (3,937 ASCs × 15.75 hours × $36.58 per hour). Aside from burden associated with information collection however, we anticipate that facilities will experience a general burden and cost reduction associated with these removals stemming from no longer having to review and track program requirements associated with this measure.

Therefore, as noted in section XIX.C.4. of this final rule with comment period, we believe the removal of a total of one measure (ASC–10) from the ASCQR measure set for the CY 2021 payment determination will result in a total annual reduction in information collection burden of 62,008 hours and $2,268,244.

D. Effects of the Update to the HCAHPS Survey Measure in the Hospital IQR Program

As discussed in section XVI. of this final rule with comment period, we are finalizing a modified version of our proposals regarding the Communication About Pain questions from the HCAHPS Survey in the Hospital IQR Program. Instead of removing the questions effective with January 2022 discharges, for the FY 2024 payment determination and subsequent years as proposed, we are finalizing to remove them effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years. In addition, instead of publicly reporting the data in October 2022 and then subsequently discontinuing as proposed, we are finalizing that we will not publicly report the data collected from the Communication About Pain questions at all. We anticipate that the removal of these questions will result in only a nominal and temporary increase on the information collection burden on providers associated with adjusting the survey instrument and instructional materials, and a burden decrease for survey respondents. We note that the burden estimate for the Hospital IQR Program under the program's OMB control number 0938–1022 excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981. We address the anticipated information collection burden reduction in section XVIII.D. of this final rule with comment period.

E. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As described in section XVII.B. of this final rule with comment period, we are not finalizing our proposals made in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503) to remove two chart-abstracted, NHSN measures, the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (PCH–5/NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (PCH–4/NQF #0139) from the PCHQR Program beginning with the FY 2021 program year.

We estimate that not finalizing our proposals to remove the CAUTI and CLABSI measures will result in no changes to our previously finalized burden estimates under the PCHQR Program. We refer readers to section XIX.E. of this final rule with comment period for a discussion of the information collection estimates for the CAUTI and CLABSI measures. We refer readers to section XIV.B.4. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41694 through 41695) and Appendix A, section I.L. of that final rule (83 FR 41772) for more detail regarding our previously finalized information collection and burden estimates under the PCHQR Program.

F. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review a rule, we assumed that the number of commenters on the CY 2019 OPPS/ASC proposed rule (2,994) will be the number of reviewers of this final rule with comment period. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule with comment period. It is possible that not all commenters will review this final rule with comment period in detail, and it is also possible that some reviewers will choose not to comment on this final rule with comment period. Nonetheless, we believe that the number of commenters on the CY 2019 OPPS/ASC proposed rule will be a fair estimate of the number of reviewers of this final rule with comment period. In the CY 2019 OPPS/ASC proposed rule (83 FR 37237), we welcomed any comments on the approach in estimating the number of entities that will review the proposed rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the proposed rule and this final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule. In the proposed rule, we sought public comments. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 8 hours for the staff to review half of this final rule with comment period. For each facility that reviewed this final rule with comment period, the estimated cost is $859.04 (8 hours × $107.38). Therefore, we estimated that the total cost of reviewing this final rule with comment period is $2,571,966 ($859.04 × 2,994 reviewers).

G. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals, ASCs and CMHCs are small entities as that term is used in the RFA. For purposes of the RFA, most hospitals are considered small businesses according to the Small Business Administration's size standards with total revenues of $38.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $15 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at: *http://www.sba.gov/content/table-small-business-size-standards*.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period will increase payments to small rural hospitals by less than 3 percent; therefore, it should not have a significant impact on approximately 616 small rural hospitals.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

H. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $150 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this final rule with comment period, will be a deregulatory action for the purposes of Executive Order 13771. We estimate that this final rule with comment period will generate $22.52 million in annualized cost savings at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

J. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2019. Table 62 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 0.6 percent increase in payments for all services paid under the OPPS in CY 2019, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, the finalized off-campus provider-based department clinic visits payment policy, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2019.

The updates to the ASC payment system for CY 2019 will affect each of the approximately 5,500 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year. Table 63 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.1 percent for CY 2019.

XXII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State

law, or otherwise have a Federalism implication. As reflected in Table 62 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 0.5 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 2. Section 416.164 is amended—
■ a. By revising paragraph (a)(4);
■ b. In paragraph (b)(5), by removing the period and adding in its place ''; and''; and
■ c. By adding paragraph (b)(6).

The revision and addition read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(4) Drugs and biologicals for which separate payment is not allowed under the hospital outpatient prospective payment system (OPPS), with the exception of non-opioid pain management drugs that function as a supply when used in a surgical procedure;

* * * * *

(b) * * *

(6) Non-opioid pain management drugs that function as a supply when used in a surgical procedure.

* * * * *

■ 3. Section 416.171 is amended by revising paragraphs (a)(2) and (b)(1) and (2) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) *Conversion factor for CY 2009 and subsequent calendar years.* The conversion factor for a calendar year is equal to the conversion factor calculated for the previous year, updated as follows:

(i) For CY 2009, the update is equal to zero percent.

(ii) For CY 2010 through CY 2018, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(iii) For CY 2019 through CY 2023, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2024 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2023, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2024 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(D) The application of the provisions of paragraph (a)(2)(viii)(A), (B), or (C) of this section may result in the update being less than zero percent for a year, and may result in payment rates for a year being less than the payment rates for the preceding year.

(b) * * *

(1) Covered ancillary services specified in § 416.164(b), with the exception of radiology services and certain diagnostic tests as provided in § 416.164(b)(5) and non-opioid pain management drugs that function as a supply when used in a surgical procedure as provided in § 416.164(b)(6).

(2) The device portion of device-intensive procedures, which are procedures that—

(i) Involve implantable devices assigned a CPT or HCPCS code;

(ii) Utilize devices (including single-use devices) that must be surgically inserted or implanted; and

(iii) Have a HCPCS code-level device offset of greater than 30 percent when calculated according to the standard OPPS ASC ratesetting methodology.

* * * * *

■ 4. Section 416.320 is amended by revising paragraph (c) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(c) *Removal of quality measures*—(1) *General rule for the removal of quality measures.* Unless a measure raises specific safety concerns as set forth in paragraph (b) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the ASCQR Program to allow for public comment.

(2) *Factors for consideration of removal of quality measures.* CMS will

weigh whether to remove measures based on the following factors:

(i) *Factor 1.* Measure performance among ASCs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (topped-out measures);

(ii) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(iii) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(iv) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(v) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(vi) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(vii) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(viii) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(3) *Criteria to determine topped-out measures.* For the purposes of the ASCQR Program, a measure is considered to be topped-out under paragraph (c)(2)(i) of this section when it meets both of the following criteria:

(i) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an ASC's measure is within two times the standard error of the full data set); and

(ii) A truncated coefficient of variation less than or equal to 0.10.

(4) *Application of measure removal factors.* The benefits of removing a measure from the ASCQR Program will be assessed on a case-by-case basis. A measure will not be removed solely on the basis of meeting any specific factor or criterion.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 6. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*10*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*10*) For calendar year 2019, a multifactor productivity adjustment (as determined by CMS) and 0.75 percentage point.

* * * * *

■ 7. Section 419.46 is amended by revising paragraphs (a)(1) through (3) and adding paragraph (h) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) * * *

(1) Register on the QualityNet website before beginning to report data;

(2) Identify and register a QualityNet security administrator as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit at least one data element.

* * * * *

(h) *Retention and removal of quality measures under the Hospital OQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital OQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (h)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the QualityNet website.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (h)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital OQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital OQR Program, a measure is considered to be topped-out under paragraph (h)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital OQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

Dated: October 26, 2018.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 29, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–24243 Filed 11–2–18; 8:45 am]

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Part III

Department of Transportation

Federal Railroad Administration

49 CFR Parts 229, 231, 236, et al.
Passenger Equipment Safety Standards; Standards for Alternative Compliance and High-Speed Trainsets; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 229, 231, 236, and 238

[Docket No. FRA–2013–0060, Notice No. 3]

RIN 2130–AC46

Passenger Equipment Safety Standards; Standards for Alternative Compliance and High-Speed Trainsets

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule amends FRA's passenger equipment safety standards using a performance-based approach to adopt new and modified requirements governing the construction of conventional- and high-speed passenger rail equipment. This final rule adds a new tier of passenger equipment safety standards (Tier III) to facilitate the safe implementation of nation-wide, interoperable high-speed passenger rail service at speeds up to 220 mph. While Tier III trainsets must operate in an exclusive right-of-way without grade crossings at speeds above 125 mph, these trainsets can share the right-of-way with freight trains and other tiers of passenger equipment at speeds not exceeding 125 mph. This final rule also establishes crashworthiness and occupant protection performance requirements in the alternative to those currently specified for Tier I passenger trainsets. Together, the Tier III requirements and Tier I alternative crashworthiness and occupant protection requirements remove regulatory barriers and enable use of new technological designs, allowing a more open U.S. rail market. Additionally, the final rule increases from 150 mph to 160 mph the maximum speed for passenger equipment that complies with FRA's Tier II requirements.

DATES: *Effective date.* This final rule is effective January 22, 2019.

Incorporation by reference. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of January 22, 2019.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or visit the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140 on the Ground level of the West Building, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Devin Rouse, Staff Director, U.S. Department of Transportation, Federal Railroad Administration, Office of Railroad Safety, Passenger Rail Division, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–493–6185); or Michael Hunter, Attorney Adviser, U.S. Department of Transportation, Federal Railroad Administration, Office of Chief Counsel, 1200 New Jersey Avenue SE, Washington, DC 20590 (telephone: 202–493–0368).

SUPPLEMENTARY INFORMATION:

Common Abbreviations

AAR Association of American Railroads
APTA American Public Transportation Association
AW0 ready-to-run weight, empty
CEM crash energy management
CFR Code of Federal Regulations
CG center of gravity
EN EuroNorm
ETF Engineering Task Force
FE finite element
FEA finite element analysis
FRA Federal Railroad Administration
g gravitational acceleration (32.2 feet/second/second)
HSR high-speed rail
in inch(es)
kip kilopound(s)
kN kilo-Newton(s)
kph kilometer(s) per hour
lbf pound(s)-force
mph mile(s) per hour
ms millisecond(s)
MU multiple-unit
OVI occupied volume integrity
PTC positive train control
RIA regulatory impact analysis
ROW right-of-way
RSAC Railroad Safety Advisory Committee
ITM inspection, testing, and maintenance
PTEP Passenger Train Emergency Preparedness
PESS Passenger Equipment Safety Standards
U.S.C. United States Code
UIC International Union of Railways

Table of Contents

I. Executive Summary

Having considered the public comments in response to FRA's December 6, 2016, proposed rule on standards for alternative compliance and high-speed trainsets, see 81 FR 88006, FRA issues this final rule amending the Passenger Equipment Safety Standards, 49 CFR part 238. This final rule is the product of consensus reached by FRA's Railroad Safety Advisory Committee (RSAC), which accepted the task of reviewing passenger equipment safety needs and programs and recommending specific actions that could be useful to advance the safety of passenger service, including the development of regulatory requirements for the next generation of high-speed trainsets. The RSAC established the Passenger Safety Working Group (''PSWG'' or ''Working Group'') to handle this task and develop recommendations for the full RSAC to consider. In September 2009, the Working Group in turn established the Engineering Task Force (''ETF'' or ''Task Force'') for the purpose of producing a set of technical criteria and procedures to evaluate passenger rail equipment based on alternative designs. This work led to the development of the report entitled ''Technical Criteria and Procedures for Evaluating the Crashworthiness and Occupant Protection Performance of Alternatively Designed Passenger Rail Equipment for Use in Tier I Service'' (''Technical Criteria and Procedures Report'' or ''Report'').[1] The guidance in the Technical Criteria and Procedures Report has assisted railroads and rolling stock manufacturers who have petitioned FRA for waivers from strict compliance with FRA's Tier I passenger equipment crashworthiness standards, and has been useful to FRA in

[1] U.S. Department of Transportation Report No. DOT–FRA–ORD–11/22. Washington, DC: Federal Railroad Administration, Office of Railroad Policy Research and Development, October 2011, available at *http://www.fra.dot.gov/eLib/details/L01292#p4_z50_gD_lRT*.

evaluating such petitions. In addition to developing the criteria in the Report, the ETF's task was expanded to develop formal recommendations to the full RSAC for adopting these alternative crashworthiness and occupant protection criteria into FRA's regulations and to establish minimum safety requirements for the next generation of high-speed trainsets, capable of operating at speeds of up to 220 mph, classified as Tier III passenger equipment. The ETF reached consensus on recommending the adoption of these alternative crashworthiness criteria in 49 CFR part 238 for Tier I passenger equipment. The ETF also reached consensus on criteria for Tier III passenger equipment, specifically trainset structure, side-window glazing, brake systems, interior fittings and surfaces, certain emergency systems and cab equipment, and cab glazing (with the exception of ballistic penetration resistance). The ETF further reached consensus on the definition of Tier III, including when Tier III equipment can operate on shared infrastructure and when the equipment must operate in an exclusive right-of-way. On June 14, 2013, the full RSAC voted to recommend the consensus items to FRA's Administrator, as the basis for a formal rulemaking. This final rule is based on these RSAC recommendations.

This final rule establishes requirements in three main subject areas: (1) Tier III trainset safety standards; (2) alternative crashworthiness and occupant protection performance requirements for Tier I passenger equipment; and (3) the maximum authorized speed for Tier II passenger equipment. The following is a brief overview of the rule organized by subject area and a summary of its economic impact.

Tier III Trainset Safety Standards

This final rule defines Tier III passenger train operations and outlines the minimum safety standards for the use of such trainsets in the United States, focusing on core structural and critical system design criteria. FRA intends for this final rule to facilitate the safe implementation of interoperable high-speed rail service, and enable the use of common infrastructure and promote other efficiencies. The Tier III operating environment is unique by design. Tier III passenger trains are permitted to operate in a shared right-of-way (one shared with freight trains and other tiers of passenger equipment) at speeds up to 125 mph, but must operate in an exclusive right-of-way without grade crossings at speeds exceeding 125 mph, up to 220 mph. The requirements provide for the sharing of rail infrastructure among various types of rail equipment, especially in more urban areas, while providing for dedicated passenger rail service at maximum speeds up to 220 mph.

This final rule also establishes requirements for Tier III trainset structure, window glazing, brake systems, interior fittings and surfaces, certain emergency systems (including window egress and rescue access requirements), and certain cab equipment. To support operational compatibility, the Tier III trainset crashworthiness and occupant protection requirements are predominantly based on the alternative crashworthiness and occupant protection requirements for Tier I passenger equipment and are intended to safely apply to operations at speeds up to 220 mph in a dedicated environment as approved by FRA. Specialized RSAC task groups developed the requirements for braking systems and cab glazing by focusing on the development of performance-based requirements that could be implemented in a technology-neutral manner, wherever possible.

To develop their recommendations, the ETF and full RSAC considered the latest trainset designs and technology available globally, and adapted their recommendations in a manner consistent with the North American operating environment. The intent of these requirements is to ensure that safety and reliability are paramount, while incorporating elements from the most advanced, service-proven technology available throughout the world.

Alternative Crashworthiness Requirements for Tier I Passenger Trainsets

As noted above, FRA is codifying a set of technical evaluation criteria the ETF developed as guidance for those seeking to demonstrate that alternative crashworthiness and occupant protection performance requirements for Tier I passenger trainsets provide a level of safety equivalent to the existing requirements in part 238. FRA intends for the alternative technical criteria to allow the industry greater flexibility to use more contemporary design techniques and more fully apply emerging technology, including crash energy management (CEM) technology, without requiring a waiver of compliance for operating the equipment. The technical criteria are based on established international standards and significant research and testing conducted by the industry and DOT's John A. Volpe National Transportation Systems Center (Volpe Center) over the past 25 years. Codifying the technical criteria dovetails with alternative crashworthiness performance requirements FRA earlier established in part 238 for the front-end structures of cab cars and multiple-unit (MU) locomotives (75 FR 1180), thereby broadening application of such requirements to other main structures.

Tier II Maximum Authorized Speed

On March 13, 2013, FRA issued a final rule (78 FR 16052) to amend the Federal Track Safety Standards to promote the safe interaction of rail vehicles and the tracks they operate on at speeds up to 220 mph. That final rule revised the track geometry and safety limits for various track classes, extended the limits for the highest track speeds from 200 to 220 mph (Class 9 track), and affirmed that the maximum authorized speed for Class 8 track is 160 mph. This final rule establishes the maximum authorized operating speed for Tier II passenger equipment consistent with the limits for Class 8 track. However, it is important to note that existing Tier II operations FRA has approved to operate at speeds up to 150 mph are still required to provide sufficient testing and vehicle/track interaction performance data required under 49 CFR 213.329 and 238.111, and obtain FRA approval before any operations occur at the new maximum authorized speed of 160 mph.

Economic Analysis

This final rule expands and makes more flexible FRA's Passenger Equipment Safety Standards. FRA believes this final rule will have a net cost savings effect on the passenger rail industry and society as a whole, along with safety benefits.

Specifically, the final rule will generate cost savings benefits by enabling high-speed rail operators to avoid new right-of-way acquisition and infrastructure construction for dedicated rail lines in dense urban areas. This is possible because the final rule allows such trains to travel on existing, non-dedicated rail lines, although at slower speeds than permissible for travel on dedicated rail lines.

For traditional passenger rail operations, there are both operational and safety benefits resulting from this final rule. Not issuing the rule would increase costs associated with the acquisition of new passenger trains and could delay new U.S. passenger rail infrastructure projects. The final rule ensures existing and future alternative trainset designs can operate in the U.S.

railroad environment on a widespread basis, beyond the constraints that have been imposed by FRA regulations. This helps avert perpetuating a patchwork of waivers in the U.S. passenger rail market that would, in turn, perpetuate the current unattractiveness of the U.S. passenger equipment market to manufacturers. The final rule allows U.S. trainsets to use technological advances for safety compliance purposes in a way that was previously restricted under the former regulations.

There will also be safety benefits associated with improvement of the existing rail infrastructure to accommodate the operation of new high-speed rail equipment in shared rights-of-way.[2] Additionally, as the requirements herein are largely performance-based standards and not prescriptive requirements, equipment benefits will be generated by passenger rail operators being able to adopt service-proven, safety-equivalent technology and practices and apply future technological advancements.

Over a 30-year period, FRA estimates quantifiable cost savings range from a present value of between $512.5 million to $1.1 billion (when discounted at a 7-percent rate) or between $790.1 million to $1.6 billion (when discounted at a 3-percent rate).[3] Annualized cost savings of this rule are expected to be between $41.3 million and $85.8 million when discounted at a 7-percent rate and between $40.3 million and $84.0 million when discounted at a 3-percent rate.

Over the same 30-year period, FRA estimates the industry will incur costs ranging between $227.7 to $523.3 million (when discounted at a 7-percent rate) or between $351.3 to $808.8 million (when discounted at a 3-percent rate). Annualized costs of this rule are expected to be between $18.4 million and $42.2 million when discounted at a 7-percent rate and between $17.9 million and $41.3 million when discounted at a 3-percent rate. All quantified costs would be for testing and analysis to demonstrate compliance with either the Tier I alternative or Tier III standards.

Over the 30-year period of the analysis, FRA estimates discounted net regulatory cost savings will be between $438.8 million (low range) and $837.8 million (high range) discounted at 3 percent; net regulatory cost savings will be between $284.8 million (low range) and $541.9 million (high range), discounted at 7 percent. Annualized net regulatory cost savings total between $22.4 million and $42.7 million when discounted at a 3-percent rate and between $22.9 million and $43.7 million when discounted at a 7-percent rate.

NET REGULATORY COST SAVINGS

[Quantified estimates using a 30-year period; $ in millions]

Description	Discounted 3%	Discounted 7%
High Range		
Total Costs	$808.8	$523.3
Total Cost Savings	1,646.7	1,065.2
Total Net Cost Savings	837.8	541.9
Annualized Net Cost Savings	42.7	43.7
Low Range		
Total Costs	351.3	227.7
Total Cost Savings	790.1	512.5
Total Net Cost Savings	438.8	284.8
Annualized Net Cost Savings	22.4	22.9

The rulemaking will provide an optional alternative, not a mandate, for railroads to use a different type or design of passenger equipment in Tier I service and will not impose any burden on existing rolling stock or new equipment qualifying under existing regulations. Similarly, the rulemaking will provide a framework for railroads to operate equipment in new Tier III service—it will not impose any burden on existing rolling stock or new equipment qualifying under existing regulations.

Alternatives Considered

One of the main purposes of the final rule is to provide a set of minimum Federal safety requirements for safe operation in the U.S. rail environment of passenger equipment platforms designed to contemporary engineering standards outside of the U.S. Traditionally, U.S. railroad safety regulations evolved as a consequence of specific accidents scenarios, which have led to the identification of specific risks in the operating environment.[4] As FRA stated in its 1999 Passenger Equipment Safety Standards (PESS) final rule, the railroad operating environment in the United States generally requires passenger equipment to operate commingled with very heavy and long freight trains, often over track with frequent grade crossings used by heavy highway equipment. *See* 64 FR 25540, 25541 (May 12, 1999). European passenger operations, on the other hand,

[2] For example, the shared rail infrastructure is presumed to be better maintained to accommodate the new Tier III equipment, and thus all rail traffic operating over that shared infrastructure will benefit from track maintained to tighter tolerances for higher speeds under FRA's track safety standards at 49 CFR part 213. Track that was once maintained to Class 4 or 5 tolerances, may now be maintained to Class 6 or 7 tolerances.

[3] Tier III costs and cost savings are uncertain because they are based on assumptions regarding the future growth of high-speed rail operations and how those operations will be incorporated into the U.S. rail network. It is possible that all costs, cost savings, and benefits relating to Tier III systems, including equipment and infrastructure, will be zero. This could occur if no high-speed rail projects come to fruition over the forecasted horizon. Further, the estimated infrastructure cost savings depend on the assumption of not having to build dedicated HSR track for the whole system (*i.e.,* they represent savings from being able to operate HSR using shared infrastructure). Tier I cost savings from adopting performance-based standards are challenging to quantify, as estimates are based on projecting future changes. However, given that the new regulation's performance standards provide an alternative to more design-based standards, operators would voluntarily comply only if they found it beneficial to do so. The estimated figures in the Regulatory Impact Analysis (RIA) are provided for expository purposes. For both Tier III and Tier I, if the actions that trigger cost savings are not taken, the costs would not be incurred, as the costs and cost savings are two sides of the same actions.

[4] Passenger Equipment Safety Standards, Notice of Proposed Rulemaking, 62 FR 49728, 49729–49731 (Sep. 23, 1997) (discussing differences between the European and U.S. rail operating environments, and describing a range of passenger rail accidents demonstrating the need for comprehensive, passenger equipment safety standards).

are intermingled with freight equipment of lesser weight than in North America. In many cases, highway-rail grade crossings also pose lesser hazards to passenger trains in Europe due to lower highway vehicle weight.

While FRA seeks to continue ensuring the safety risks are adequately addressed for the operating environment, the final rule places special emphasis on measures to avoid those risks rather than simply mitigating them. Importantly, this final rule allows the use of additional types of rolling stock design, which will enable innovation and provide railroads the flexibility to purchase equipment designed to more performance-based and modern requirements. The rule also permits carriers to move forward with a new tier of higher speed rail.

The alternatives FRA considered in establishing the safety requirements for Tier III trainsets are based on European and Japanese industry standards. These options provide a continuum of safety requirements for a range of aspects such as: Varying levels of regulation, market accessibility, benefits and costs, and operational efficiency and safety. FRA prepared a high-level cost comparison of those options based on the key attributes of the alternatives and the effect of those attributes on societal welfare and the regulatory purpose. FRA compared the technical requirements of other established high-speed rail standards to illustrate the primary differences, not make a direct comparison between comparable requirements or standards.

In Europe, passenger rail equipment crashworthiness and occupant protection design standards have been largely standardized by EuroNorms.[5] FRA concluded that there are no significant differences between trains built to the design standards contained in EuroNorms and trains built to meet the crashworthiness and occupant protection requirements in the final rule. FRA estimates that on average trainset prices will increase $310,250 (0.62 percent) per trainset to meet the Tier III requirements in this final rule.

In Japan, railroad safety regulation is governed by the Railway Bureau, Ministry of Land, Infrastructure and Transport, and is codified in the Technical Regulatory Standards on Railways.[6] These technical standards are primarily performance-based and railways have the obligation to conform their operations, equipment, and infrastructure to these standards. In the case of its high-speed rail system, the Tokaido Shinkansen, the railway transports only passengers; the rail line is entirely dedicated to high-speed rail with no conventional trains operating and has full grade separation. These are the significant differences underlying the design of Tokaido Shinkansen trainsets operating in Japan when compared to passenger trainsets currently operating in the U.S. The key to the Japanese high-speed rail network's ongoing safety performance and reliability is the principle of crash avoidance. Modifying this advanced Japanese high-speed trainset to comply with the new Tier III requirements would result in significant additional costs to be interoperable in the U.S. rail system; FRA estimates $4.7 million per trainset. European trains generally would not need carbody, truck, suspension, or brake modifications to comply with the Tier III requirements. However, either the analysis used to demonstrate compliance of the train safety features or components would require modification, or minor design modification(s) would likely be needed, or both.[7] These differences are illustrated in the following:

SUMMARY OF POTENTIAL CHANGES FOR EQUIPMENT DESIGNED TO EUROPEAN STANDARDS TO COMPLY WITH FINAL RULE IN THE U.S.

Engineering analysis difference	Minor modifications required
• Quasi static compression	• Structural integrity of non-cab end.
• Dynamic collision scenario	• Interior fixture attachment.
• Override protection	• Seat crashworthiness.
• Fluid entry inhibition	• Luggage racks.
• Roof and side structure integrity	• Emergency window egress & rescue access windows.
• Glazing	• Emergency lighting.
	• Alerters.

The RIA that accompanies this final rule contains an analysis of regulatory alternatives FRA considered. Specifically, the analysis compares at a general level the costs and benefits of the Tier III requirements to both European and Japanese standards for high-speed trains. The analysis concludes that a hypothetical $50 million European high-speed trainset could be modified to comply with the Tier III requirements with only minor structural modifications and, as indicated above, at little additional cost—about $310,000 per trainset. Modifications are expected to ensure such trainsets safely operate in a U.S. setting. Due to the lack of historical safety information for operations at Tier III speeds in the U.S., FRA was unable to estimate the incremental safety benefit that would be provided by the Tier III requirements as compared to the European technical standards. However, these new requirements are supported by the recommendation of the full RSAC and FRA is confident about the cost-beneficial nature of the final rule. Additionally, the analysis concludes that a hypothetical $50 million Tokaido Shinkansen Japanese high-speed trainset would need significant structural modifications, including those to the carbody, trucks, and suspension, to comply with the Tier III requirements, and, as indicated above, would incur significant additional costs—about $4.7 million per trainset.

FRA is unable to provide an estimate of the expected incremental benefit of the Tier III requirements over the alternatives, but FRA believes these additional costs are justified by the nature of the risks within the U.S. rail operating environment and RSAC's recommendations. Tier III trains in the U.S. will share track with other rail operations, including heavy and long

[5] EuroNorms title derived: ''Standard'' is ''norme'' in French and ''norm'' in German. *https://www.cen.eu/work/ENdev/whatisEN/Pages/default.aspx.*

[6] *http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/14.pdf.*

[7] A discussion of the rationale supporting each of the structural requirements under the ''Minor modifications required'' column in the ''Summary of potential changes for equipment designed to European standards to comply with final rule in the U.S.'' table is available under the section-by-section analysis contained in the NPRM. *See* 81 FR 88006, 88027–88028, 88034–88038 (Dec. 6, 2016). As discussed in the NPRM, each requirement was determined as necessary to achieve an equivalent level of safety as provided by conventional Tier I equipment under 49 CFR part 238, subpart C.

freight trains, and operate on track with highway-rail grade crossings and the accompanying risks of colliding with trucks and other highway vehicles.

FRA conducted a qualitative analysis comparing the final rule's Tier I alternative requirements to two alternatives: Not taking any regulatory action or adopting existing international design standards. As discussed in the RIA, trainsets compliant with international design standards (such as European or Japanese) would require extensive modifications to meet Tier I requirements if FRA elected to take no regulatory action. However, under the new Tier I alternative requirements, FRA believes the costs associated with compliance will be similar to those discussed for Tier III equipment.

A second alternative would be to codify EuroNorms as Federal regulations, instead of the new Tier I alternative requirements. This option opens the possibility for manufacturers to accrue savings from fewer modifications; however, such an option would require manufacturers to expend resources that favor a particular technology or approach to equipment design. Additionally, codifying EuroNorms in lieu of the final rule would potentially have required equipment designed to a different standard to incur certain costs related to modifying the equipment to bring it into compliance.

Consequently, regardless of the requirements codified, manufacturers would likely have to modify trainsets to meet the regulatory requirements specified. Importantly, trainsets meeting only a European standard (or Japanese or other international standard) would not be interoperable with existing U.S. passenger or freight equipment. Therefore, this equipment could only operate on an exclusive right-of-way, unable to take advantage of existing infrastructure.

FRA requested and received no public comment on the alternatives presented and discussed. For further discussion, please also see the RIA's ''Alternatives Considered'' section, in which FRA presents more detailed discussion of the impact of the alternatives considered.

FRA did consider the alternative of standalone HSR systems (not physically connected to the general railroad system) operating on an exclusive right-of-way, which would use passenger equipment that complies with European or other international standards but not necessarily with FRA's new requirements. For the reasons discussed below, FRA declined to pursue this alternative. A major tenet of this final rule is to safely facilitate the implementation of nationwide, interoperable HSR service. Standalone systems operating equipment not compliant with FRA's passenger equipment safety standards would significantly limit the interoperability of HSR service. When developing these requirements, FRA did not envision a network of standalone, non-interoperable HSR systems comprising the nationwide network.

Additionally, it would be very costly for a standalone system to attempt to connect with major metropolitan areas because those standalone systems could not take advantage of a major regulatory savings—operating over existing infrastructure. FRA determined that two-thirds to four-fifths of the regulatory cost savings are due to infrastructure cost avoidance for operations electing to use Tier I alternative or Tier III equipment. In particular, interoperability will allow HSR operators to reach into major metropolitan areas where building new, exclusive rights-of-way may not be feasible due to land density, environmental, and other considerations.

An advantage of the standalone alternative is that an individual railroad system could optimize its operations to high levels of performance without necessarily having to adhere to requirements generally applicable to railroad systems in the U.S. However, for such a project to attain that level of performance, it would have to optimize the design of the entire system, not only the passenger equipment. Basically, a standalone system would have to bring together all the other aspects of railroad safety (such as operating practices, signal and train control, and track) that must be applied to the individual system. Given that such an approach covers more than passenger equipment, and would likely necessitate particular right-of-way intrusion protection and other safety requirements not adequately addressed in FRA's regulations, FRA continues to believe that addressing proposals for standalone HSR systems on a case-by-case basis and comprehensively (such as through a rule of particular applicability or other specific regulatory action(s)) is prudent because of the small number of potential operations and the potential for significant differences in their design. Entities considering such operations voluntarily assume the higher costs of building new infrastructure, knowing they cannot take advantage of the cost savings from sharing existing infrastructure.

II. Statutory and Regulatory Background

A. Statutory Background

In September 1994, the Secretary of Transportation (Secretary) convened a meeting of representatives from all sectors of the rail industry with the goal of enhancing rail safety. As one initiative of this Rail Safety Summit, the Secretary announced that DOT would begin developing safety standards for rail passenger equipment over a five-year period. In November 1994, Congress adopted the Secretary's schedule for implementing rail passenger equipment safety regulations and included it in the Federal Railroad Safety Authorization Act of 1994 (the Act), Public Law 103–440, 108 Stat. 4619, 4623–4624 (November 2, 1994). In the Act, Congress also authorized the Secretary to consult with various organizations involved in passenger train operations for purposes of prescribing and amending these regulations and to issue orders under it. *See* section 215 of the Act (codified at 49 U.S.C. 20133).

B. Implementation of the 1994 Passenger Safety Rulemaking Mandate

On May 4, 1998, under section 215 of the Act, FRA published the Passenger Train Emergency Preparedness final rule (PTEP). *See* 63 FR 24629. The PTEP contained minimum Federal safety standards for the preparation, adoption, and implementation of emergency preparedness plans by railroads connected with the operation of passenger trains, including freight railroads hosting the operations of passenger rail service. The rule also established specific requirements for passenger train emergency systems and contained specific requirements for participation in debrief and critique sessions following emergency situations and full-scale simulations.

On May 12, 1999, FRA published the PESS final rule. *See* 64 FR 25540. The PESS established comprehensive safety standards for railroad passenger equipment including requirements for carbody structure and fire safety. FRA subsequently amended the PESS to address petitions seeking FRA's reconsideration of certain requirements contained in the rule. In response to the petitions, FRA grouped issues together and published three sets of amendments to the final rule. *See* 65 FR 41284, Jul. 3, 2000; 67 FR 19970, Apr. 23, 2002; and 67 FR 42892, June 25, 2002.

Since then, FRA has engaged in a number of rulemakings to amend and enhance its passenger safety requirements. On October 19, 2006, FRA

published a final rule addressing various requirements on the inspection, testing, and operation of passenger equipment, and the attachment of safety appliances. *See* 71 FR 61835. On February 1, 2008, FRA published the Passenger Train Emergency Systems final rule promoting passenger occupant safety by addressing emergency communication, emergency egress, and rescue access requirements. *See* 73 FR 6370. FRA also established additional requirements for passenger train emergency systems on November 29, 2013, see 78 FR 71785, revised and clarified its PTEP regulations on March 31, 2014, see 79 FR 18128, and established new standards to improve the integrity of passenger train exterior side door safety systems on December 7, 2015, see 80 FR 76118.

On January 8, 2010, FRA published a final rule enhancing requirements for the structural strength of the front end of cab cars and MU locomotives. *See* 75 FR 1180. FRA included energy-absorption requirements in the 2010 rulemaking to address traditional cab car and MU locomotive designs, with very strong underframes and relatively weaker superstructures, because it is vitally important to provide protection to crewmembers and passengers if the superstructure is impacted. In that rulemaking, FRA applied mature technology and design practice to extend requirements from linear-elastic to elastic-plastic and provided descriptions of allowable deformations without complete failure of the system. Although FRA believed at the time of the rulemaking that the alternative performance requirements would principally apply to shaped-nose equipment designs or CEM designs, or both, FRA also intended for them to apply to any conventional equipment design, as an alternative to the linear-elastic approach. In particular, the alternative performance requirements allow innovative designs that protect the occupied volume for its full height, even without traditional full-height collision and corner post structures, and the rule has been applied to such innovative end frame designs and traditional end frame designs.

III. Development of the Final Rule

This final rule is primarily based on consensus recommendations from the RSAC.[8] *See* 81 FR 88006, 88013. Those recommendations were developed over many years, and began in 2009 when FRA elected to develop, in consultation with the RSAC, alternative criteria and procedures to assess the crashworthiness and occupant protection performance of rail passenger equipment applicable to a wide range of equipment designs to be used in Tier I service. Accordingly, the ETF [9] was established in September 2009, charged with the mission of producing a set of technical criteria and procedures for evaluating petitions for waivers from (or, as appropriate under § 238.201(b), approval of alternative compliance with) one or more of the Passenger Equipment Safety Standards. This work led to the development of the Technical Criteria and Procedures Report, published in 2011. The technical evaluation criteria and procedures in the Report provided a means of establishing whether equipment of an alternative design would result in at least equivalent performance to that of equipment designed in accordance with the structural standards in 49 CFR part 238.

After the ETF developed the Report, the task of the ETF was expanded to: (1) Develop formal recommendations to the full RSAC to adopt the alternative crashworthiness criteria into FRA's regulations; and (2) establish minimum safety requirements for the next generation of high-speed trainsets able to operate at speeds up to 220 mph,[10] classified as Tier III passenger equipment. The work of the ETF and full RSAC culminated with the publication of the NPRM on December 6, 2016. Please see the Technical Background and Overview section of the NPRM, section III, for a more comprehensive discussion on the development of these requirements at 81 FR 88006, 88013–88017.

The comment period was initially scheduled to close on February 6, 2017. However, in a December 12, 2016 letter, APTA requested a 30-day extension of the NPRM's comment period. APTA stated it needed additional time to thoroughly review the NPRM, and review and consolidate comments on the NPRM from its members and affiliates. On February 13, 2017, FRA published a notice in the **Federal Register** reopening the comment period until March 21, 2017. *See* 82 FR 10449. A description and summary of the comments received on the NPRM is discussed below under section IV, Discussion of Comments and Conclusions.

To further benefit from the input of the ETF, FRA convened a meeting of the ETF on May 16–18, 2017, in Washington, DC.[11] During this meeting, FRA discussed proposed responses to the comments received, which was helpful to FRA in crafting the fuller responses to the comments contained in this final rule. Accordingly, FRA did not believe it necessary to bring any issues back to the full RSAC for a formal recommendation. The only issues for which there was no consensus either did not have consensus agreement initially (cab glazing ballistic requirements, which were deferred to FRA to develop) or were generally non-

[8] The RSAC member groups are: American Association of Private Railroad Car Owners (AAPRCO); American Association of State Highway and Transportation Officials (AASHTO); American Chemistry Council; American Petroleum Institute; American Public Transportation Association (APTA); American Short Line and Regional Railroad Association (ASLRRA); American Train Dispatchers Association (ATDA); Association of American Railroads (AAR); Association of State Rail Safety Managers (ASRSM); Association of Tourist Railroads and Railway Museums; Brotherhood of Locomotive Engineers and Trainmen (BLET); Brotherhood of Maintenance of Way Employees Division (BMWED); Brotherhood of Railroad Signalmen (BRS); Chlorine Institute; Federal Transit Administration (FTA);* Fertilizer Institute; Institute of Makers of Explosives; International Association of Machinists and Aerospace Workers; International Association of Sheet Metal, Air, Rail and Transportation Workers (SMART), including the Sheet Metal Workers' International Association (SMWIA) and United Transportation Union (UTU); International Brotherhood of Electrical Workers (IBEW); Labor Council for Latin American Advancement (LCLAA);* League of Railway Industry Women;* National Association of Railroad Passengers (NARP); National Association of Railway Business Women;* National Conference of Firemen & Oilers; National Railroad Construction and Maintenance Association (NRCMA); National Railroad Passenger Corporation (Amtrak); National Transportation Safety Board (NTSB);* Railway Supply Institute (RSI); Safe Travel America (STA); Secretaria de Comunicaciones y Transporte (Mexico);* Transport Canada;* Transport Workers Union of America (TWU); Transportation Communications International Union/BRC (TCIU/BRC); and Transportation Security Administration (TSA).* *Indicates associate, non-voting membership.

[9] The ETF member groups are: AAR; AAPRCO; AASHTO, including California Department of Transportation, and Interfleet; APTA, including Alstom, Ansaldo Breda, Bombardier, Central Japan Railway Company (JRC), China South Locomotive and Rolling Stock Corporation (CSR), Denver Regional Transportation District (RTD), East Japan Railway Company, Faiveley Transport, GE Transportation, Japan International Transport Institute, Japan's Ministry of Land, Infrastructure, Transport and Tourism, Kawasaki, Keolis, KPS N.A., LIRR, LTK Engineering Services, Marsh, Metro-North, Nippon Sharyo, Parsons Brinckerhoff, PS Consulting, Safetran Systems, SEPTA, Sharma & Associates, Siemens, Southern California Regional Rail Authority (SCRRA), Stadler, STV, Talgo, Texas Central Railway, Veolia, Voith Turbo, and Wabtec; Amtrak; ASLRRA; BLET; European Railway Agency (ERA); NTSB; RSI, including Battelle Memorial Institute, and ENSCO; SMART, including SMWIA and UTU; TCIU/BRC; and Transport Canada.

[10] FRA elected 220 mph as the maximum operating speed for Tier III equipment to remain harmonious with FRA's track safety standards (49 CFR part 213). *See* 78 FR 16052, Mar. 13, 2013 (discussing the reasoning and research behind the 220-mph maximum track speed).

[11] Minutes of this meeting is part of the docket in this proceeding and is available for public inspection.

substantive in nature (the archival of AAR–RP–5104 for incorporation-by-reference). Please see the fuller discussion of each of these topics under the section-by-section analysis of the respective sections (§ 238.721, Glazing, and § 238.735, Seat crashworthiness (passenger and cab crew)).

Please note that the RSAC did not expressly consider FRA's removal of the requirement for a rule of particular applicability to conduct operations at speeds above 150 mph, as specified in subpart I of part 236 of this chapter. See the discussion of changes to § 236.1007 of this chapter in the section-by-section analysis, below. The RSAC also did not consider FRA's changes to §§ 229.3, 229.5, and 231.0 of this chapter. These changes, harmonizing references to the maximum authorized operating speed for Tier II equipment, were not expressly proposed in the NPRM as they were inadvertently omitted. See the discussion of changes to §§ 229.3, 229.5, and 231.0 of this chapter in the section-by-section analysis, below. FRA nonetheless believes the removal of language from part 236 and the harmonization of parts 229 and 231 are consistent with the RSAC recommended approach in this rulemaking.

IV. Discussion of Comments and Conclusions

As noted above, on February 13, 2017, FRA reopened the comment period for the NPRM that closed on February 6, 2017, in response to a request received from APTA. *See* 82 FR 10449 (Feb. 13, 2017). During the entire comment period, FRA received comments from two individuals and the following seven entities: Alstom Transportation, Inc. (Alstom); APTA; East Japan Railway Company (JR East); Italcertifier, SPA; LTK Engineering Services (LTK); Siemens; and Texas Central Railroad, LLC (TCRR). The comments were all supportive of the rulemaking, and FRA appreciates the commenters for the time and effort put into each of the comments received. FRA will first discuss the comments that are applicable to the rulemaking, generally. Responses to comments on specific sections of the rule are discussed in the section-by-section analysis, or in the Regulatory Impact and Notices portion of this final rule, with the provisions and statements to which they specifically relate. FRA makes clear that the order of the discussion is not meant to imply that FRA is prioritizing one commenter over another.

As noted above, following the submission of these written comments, FRA convened the Engineering Task Force to consider and discuss the comments and to help achieve a fuller understanding of the comments received and recommendations for this final rule. As a result, certain of these comments have been superseded by changes made in the rule text from the NPRM to this final rule, and they should not necessarily be understood to reflect the positions of the commenters with respect to the requirements of the final rule. Nevertheless, FRA is setting out all the comments received and is responding to each of them, either here, or in the pertinent section-by-section analysis or Regulatory Impact Notice provision, so that FRA's positions are clearly understood. In addressing these comments and developing this final rule, FRA has relied on information contained in comments, RSAC meeting minutes, memoranda, and other materials in the docket for this rulemaking.

A. General Comments

APTA, in its comment, stated that it is very supportive of the ''Tier III approach.'' APTA further stated that the Tier III crashworthiness and occupant protection requirements permit Tier III trainsets to operate in a shared right of way with conventional passenger and freight rail equipment at speeds below 125 mph (Tier I environment). This type of interoperability has the potential to have a safe and cost-effective approach to implementing high-speed rail as it permits the use of internationally service-proven high-speed rail equipment and also the use of existing infrastructure for lower speed operation. FRA appreciates APTA's support on FRA's approach to permit Tier III equipment to be interoperable at speeds not exceeding 125 mph. APTA further noted that FRA described very well an advantage of a standalone system to be the system's potential to optimize its operations to a high level of performance.

In both their comments, APTA and TCRR recommended that FRA adopt a definition for ''Tier IV system.'' For the reasons discussed in the section-by-section analysis for § 238.5, below, FRA is not including a definition for ''Tier IV system'' in this final rule. However, APTA's and TCRR's comments on this topic went beyond the definition of a Tier IV system and touched on FRA's discussion in the NPRM of Alternatives Considered under the Executive Summary. 81 FR 88006, 88009.

Additionally, APTA, as part of its comment, noted that the regulation references several APTA standards by a ''date certain'' for incorporation by reference. APTA further noted that many of those standards will be updated ''in the near future'' and recommended that the latest versions of the standards be referenced. APTA also recommended, more generally, that all existing references to APTA standards within part 238 be updated in the final rule. FRA must incorporate by reference updated technical standards according to 1 CFR part 51. To the extent possible, FRA has included for incorporation by reference the most up-to-date APTA standards that were under consideration in this rulemaking. Under the section-by-section analysis, FRA has indicated where it has revised references from the initial versions of APTA standards to refer to the most recent editions instead. With respect to updating references to APTA standards in part 238, generally, FRA will address this issue in another rulemaking effort in which FRA reviews and updates, as necessary, all references to relevant technical standards in part 238, because part 238 incorporates by reference technical standards from a number of different industry consensus organizations.

Alstom commented on § 238.15, Movement of passenger equipment with power brake defects, asking FRA if a reference for Tier III equipment will be added where there is currently a reference to Tier II. Alstom also commented more generally whether Tier II requirements will be analyzed on a case-by-case basis and extended to apply to Tier III equipment. Alstom comments on § 238.15 are outside the intended scope of this rulemaking. Due to the unique nature of Tier III equipment and operations, FRA believes that more consideration and analysis are necessary in developing appropriate regulatory requirements addressing the specific safety concerns implicated. Accordingly, FRA believes it appropriate to seek public comment on any proposal on this topic as part of a future rulemaking. In the interim, FRA will work with any proposed Tier III operation to ensure proper safeguards and procedures are in place to protect the movement of defective Tier III equipment.

Italcertifier, SPA submitted a presentation to the docket in which it outlined six comments. None of those six comments proposed any changes to regulatory text or to FRA's approach to Tier I alternative or Tier III requirements. Among its comments, Italcertifier stated that collision risk is mitigated ''by the presence and efficiency of the train protection systems'' and the crash-avoidance philosophy, and added that trains in Europe must be equipped with an onboard train control system that is integrated with the wayside signal

system. Italcertifier stated, though, that the proposed rule did not account for PTC or such other technology. However, FRA notes that PTC technology is not intended as a replacement for crashworthiness and occupant protection requirements. PTC is a performance-based system requirement that provides collision avoidance and overspeed protection technology for certain accident scenarios that complement, but do not replace, crashworthiness and occupant protection requirements. Additionally, not all accidents are PTC-preventable.

Italcertifier also commented that in Italy ''level crossings'' (highway-rail grade crossings) are not permitted at speeds exceeding 200 km/h (approximately 124 mph) but there is a movement to eliminate such crossings from track with speeds exceeding 160 km/h (approximately 100 mph). Although this has no impact on the regulatory text, FRA notes that such an approach appears consistent with FRA's treatment of grade crossings (permitted on Class 6 track, or at speeds up to 110 mph; permitted subject to FRA approval on Class 7 track, or at speeds up to 125 mph; and prohibited on Class 8 track and above, or at speeds exceeding 125 mph). *See* 49 CFR 213.347. Further, Italcertifier commented that the European standards bodies (*e.g.,* CEN or CENELEC) create technology-neutral standards, which is consistent with FRA's approach under this rule. Italcertifier also expressed its support for creating an interoperable passenger rail network, stating that the decision to have an interoperable high-speed rail system, and not a standalone system except on a case-by-case basis, is completely in line with the European position. Finally, Italcertifier commented that qualifying equipment in Italy requires a series of tests to demonstrate compliance with various European technical standards. This, too, is consistent with FRA's approach.

JR East's comment focused on the economic impacts of the proposed rule. In its comment, JR East articulated that when FRA calculates the costs of modifying Japanese equipment to meet Tier III requirements, FRA should consider not only the initial cost (which FRA estimated at $4.7 million per trainset), but also ''the total cost including operation cost, maintenance cost and the expenses for the suspension of transportation due to accidents.'' FRA has addressed this comment in section 2.1.1 of the regulatory impact analysis, which is included in the docket, and in the economic analysis discussion contained in this final rule. For purposes of the economic analysis, FRA chose to only consider the initial cost of modifying Japanese equipment to meet Tier III requirements. FRA considers that the operation, maintenance, and other related expenses would be unique to each railroad potentially operating the equipment, and therefore the differential cost would only be the expense to modify the equipment.

LTK was very supportive of the rule and the effort put forth by all involved in the ETF. LTK also expressed that the publication of the proposed rule was timely in that industry ''requires clarity'' with respect to applicable safety standards for Tier I alternative and Tier III high-speed trainsets, noting both of which must be capable of operating in mixed service with conventional passenger and freight operations at speeds below 125 mph as a result of a number of ongoing trainset procurements. LTK went on to say that the crashworthiness and occupant protection requirements contained in the proposed rule will facilitate the introduction of international passenger and high-speed trainset designs with minor modifications to enable operation in the North American rail environment. LTK also commented that it agrees with the comments APTA submitted to the docket, stating that the recommended edits in the APTA comments provide additional clarity and are consistent with the basis for consensus reached within the ETF. LTK further commented that APTA is currently in the process of reviewing and renewing its Passenger Rail Equipment Safety Standards and that, as FRA finalizes the rule, FRA should update the incorporation dates of APTA standards to the most recent dates if the standards are updated and approved through APTA prior to final rule publication. FRA makes clear it supports incorporating updated APTA standards and has incorporated by reference the most up-to-date APTA standards in this final rule consistent with the requirements of 1 CFR part 51.

Siemens' comment was very supportive of the rule and of the ETF's work on it. Siemens expressed the belief that the rule's defining of the new equipment tier, Tier III, was timely and is needed to clarify to the industry what types of trainset designs ''can get approved by the FRA.'' Siemens noted this significantly reduces risk for the industry and has its full support. Siemens also expressed its support for the comments submitted by APTA to the docket. Siemens stated it participated in the reviews leading to the submission of the APTA comments and believed they improve the NPRM.

TCRR also voiced support of the rulemaking and of the industry-developed comments submitted by APTA, noting they provide clarification on various requirements proposed in the NPRM and are consistent with the basis for consensus reached within the RSAC ETF. TCRR also submitted substantive comments on specific sections that are addressed in the section-by-section analysis, below.

In addition, FRA received comments on the rulemaking from individuals. One individual stated that he ''strongly support[s] modifying the regulations that make American trains much more expensive and slower than train across much of the rest of the world.'' The commenter urged, to the extent possible, that FRA align its regulations with other major standards (especially European standards) to enable railroads to buy ''off-the-shelf'' trainsets at much lower cost. The commenter stated that this was an easy way to start to reduce regulatory burdens and suggested that FRA's regulations be amended to grant a categorical safe harbor for any trainset that complies with the European safety requirements. FRA has long considered whether adopting European safety requirements would be practical in advancing passenger rail safety in the U.S., given the unique nature of the risks within the U.S. rail operating environment in which passenger trains share track with other rail operations, including heavy and long freight trains, and frequently operate on track with highway-rail grade crossings and the accompanying risks of colliding with trucks and other highway vehicles. 62 FR 49728, 49729–49731 (Sep. 23, 1997). In addressing the safety concerns that are present in the U.S., FRA has instead focused on developing regulations in this rulemaking that are performance-based and technology-neutral to further open the U.S. market to international experience and contemporary design techniques and to harmonize the crashworthiness and occupant protection requirements with those that are established internationally. Further, if a car builder can show that its equipment meets or exceeds the crashworthiness and occupant protection requirements as established by this rule without structural modification through proper modeling and documentation, FRA would not exclude that equipment from operating in the U.S. Specifically, FRA noted in the NPRM that it is important to recognize that differences between the FRA requirements and international technical standards do not mean that in all cases structural modifications are

necessary. Equipment designed to international standards can meet these requirements; the equipment manufacturer must only validate and provide supporting documentation that it does. *See* 81 FR 88006, 88014. Further, FRA notes that in response to its solicitation for comments on the topic of alternative approaches to regulating Tier III equipment (*i.e.,* fully adopting European standards), no international equipment manufacturer (some of whom are members of the ETF) stated that it would be better to simply adopt European crashworthiness standards or offered any other regulatory alternative to the ETF's recommended approach. Accordingly, this supports FRA's approach to addressing crashworthiness and occupant protection requirements in this rule. Further, FRA notes that the commenter's reference to a so-called ''off-the-shelf'' product is misleading, as all common product platforms are modified to fit the specific needs of the customer's specifications, which often reflects varying regulatory standards for the country or service intended.

FRA received a comment from another individual who expressed overall support for the proposed rule and wanted to accommodate NTSB recommendations to the extent possible without excluding the adoption of ''EuroNorm-like trains.'' FRA addresses NTSB's recommendations and comments, below.

B. Proposed Subpart I and the Inspection, Testing, and Maintenance Requirements for Tier III Passenger Equipment

FRA is not adopting the proposed ITM requirements under proposed subpart I in the NPRM. FRA worked with the ETF to develop a more comprehensive set of ITM requirements for Tier III equipment. Indeed, in their comments on the NPRM, both APTA and TCRR cited the likelihood that the requirements in the subpart as proposed would be subject to change based on the ETF's then-ongoing discussion of ITM requirements, and they recommended against including the requirements of proposed subpart I in this final rule.

FRA will work with any proposed Tier III operation so that ITM processes and procedures for an operation's equipment are sufficient to address all safety-critical features. FRA will be guided by the ITM program elements the ETF developed, which may be codified in a future rulemaking.

C. Proposed Subpart J and the Safe Operation Plan for Tier III Passenger Equipment

In the NPRM, FRA proposed to add and reserve a subpart J to contain the requirements for a Safe Operation Plan for Tier III Passenger Equipment (or Tier III Safe Operation Plan). As noted below, APTA commented that this subpart is unnecessary as the information requested by FRA for inclusion in a Tier III Safe Operation Plan would be available to FRA through other regulatory means. Specifically, APTA prepared a matrix recommending changes to various proposed requirements in the NPRM where it believed the desired information should be provided, including the addition of a § 238.110 (Pre-revenue qualification plan) to review specific design review elements. FRA has adopted APTA's recommendations, in whole or in part, in various sections of this final rule (see the specific section-by-section analysis, below), and has not adopted subpart J, as proposed. However, FRA intended the Tier III Safe Operation Plan to be a mechanism allowing flexibility for both the Tier III equipment manufacturer and operator to address, and FRA to review and approve, certain aspects of Tier III equipment or operations not prescriptively defined in the regulation so they can be appropriately tailored. To do so, the Tier III Safe Operation Plan would provide FRA a broad level of oversight during the equipment design period to ensure that safety issues are addressed. FRA therefore remains concerned that APTA's comments do not offer an alternative that provides FRA the same approval oversight for all Tier III equipment or operations matters initially identified for the Tier III Safe Operation Plan. For instance, FRA does not approve railroad operating rules, so referencing a railroad's operating rules to address various matters is not a suitable alternative. Without a Tier III Safe Operation Plan requirement in the rule, some other mechanism for FRA review and approval is necessary.

As noted below, APTA has suggested the addition of a new § 238.110 to handle this review and approval oversight function. However, FRA believes that further work is necessary to develop this alternate approach. The process for how FRA would provide approval is not fully addressed in APTA's proposal, including when that approval must be sought, and what, specifically, needs to be approved, including how certain Tier III operational aspects would be reviewed and approved by FRA. In the interim, FRA will work with any proposed Tier III operation on a case-by-case basis to address safety-critical matters that would otherwise have been identified for inclusion in the proposed Tier III Safe Operation Plan.

D. Comments From the NTSB

The NTSB submitted a letter to the docket asking FRA to include in the final rule provisions to address safety recommendations the NTSB has issued. Specifically, the NTSB asked FRA to add language addressing safety recommendations R–12–41, R–14–74, R–15–01, and R–15–02.

Recommendation R–12–41 arose from a grade crossing accident that occurred in Miriam, NV, in 2011, where a tractor-trailer truck struck the side of an Amtrak train that was passing through the crossing. The NTSB recommended FRA ''[r]equire that passenger railcar doors be designed to prevent fire and smoke from traveling between railcars.'' FRA notes that adding weight or tighter seals to the doors to prevent fire and smoke from traveling between railcars could cause unintended harm. Both sliding and swinging doors interact closely with the surrounding car body structure, at the hinge, track, jamb, pocket, and/or latch. Even minor distortion of that structure due to the forces of collision or derailment, or simply a change in the orientation of the door due to a car being significantly displaced from its upright position, could cause the door to fail to operate as intended. Thus, during an emergency, additional time and effort would be needed to operate the doors, delaying egress and access through those doors.

Recommendation R–14–74 arose from the overspeed derailment of a Metro-North commuter train in Spuyten Duyvil, NY, in 2013. The derailment occurred in a 6-degree left-hand curve where the maximum authorized speed was 30 mph. The train was traveling at 82 mph when it derailed. As a result of the derailment, four people died and at least 61 persons were injured. Metro-North estimated about 115 passengers were on the train at the time of the derailment. Contributing to the severity of the accident was the loss of the window glazing that resulted in the fatal ejection of four passengers from the train. The NTSB recommended FRA ''[d]evelop a performance standard to ensure that windows (*e.g.,* glazing, gaskets, and any retention hardware) are retained in the window opening structure during an accident and incorporate the standard into [49 CFR 238.221 and 238.421] to require that passenger railcars meet this standard.'' As discussed in its responses to the

NTSB,[12] FRA is taking steps to address this recommendation. However, the Metro-North accident was the result of overspeed.[13] Implementation of positive train control should eliminate such overspeed occurrences in passenger service, thereby reducing the likelihood of rollover accidents and fatalities due to ejection through window openings similar to the events involved in the Metro-North accident. At this time, though, FRA is not amending § 238.221 or § 238.421, as the NTSB's recommendations are outside the intended scope of this rulemaking.

Recommendations R–15–01 and R–15–02 arose from a train-to-train collision between two Metro-North commuter trains in Bridgeport, CT, in 2013. An eastbound train was struck by a westbound train after the eastbound had derailed. As a result of the collision, at least 65 persons were injured. Metro-North estimated about 250 passengers were on each train at the time of the accident. In R–15–01, the NTSB recommended FRA ''[r]evise [49 CFR 238.213] to require the existing forward-end corner post strength requirements for the back-end corner posts of passenger railcars.'' In R–15–02, the NTSB recommended FRA ''[r]evise [49 CFR part 238] to incorporate a certificate of construction, similar to the one found at [49 CFR 179.5], and require that the certificate be furnished prior to the in-service date of the railcar.'' FRA recognizes the importance of structurally sound passenger cars and believes it has achieved the intent of these recommendations. After fully analyzing FRA's current safety data, evaluating FRA's existing safety regulations, and reviewing the NTSB's findings, FRA determined that its current regulations do address the NTSB's underlying safety concerns.[14] FRA continues to use RSAC to identify and analyze potential safety issues and the need for further rulemaking. At this time, RSAC (and by extension, FRA) is not considering any changes to the strength requirements for passenger car corner posts.

[12] *https://www.ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-14-074.*

[13] *http://www.ntsb.gov/investigations/AccidentReports/Pages/RAB1412.aspx.*

[14] *https://www.ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-15-001 https://www.ntsb.gov/safety/safety-recs/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=R-15-002.*

V. Section-by-Section Analysis

Part 229—Railroad Locomotive Safety Standards

Subpart A—General

Section 229.3 Applicability

FRA is revising § 229.3(c) to conform the reference to Tier II maximum authorized speed with this final rule's revision to the definition of ''Tier II.'' FRA is simply changing the reference to ''150 mph'' to ''160 mph,'' reflecting the changes to the maximum authorized speed of Tier II equipment under this rule. This was not expressly discussed in the proposed rule; however, this is merely a conforming technical revision and will not impose any additional regulatory requirements or burdens on the regulated industry.

Section 229.5 Definitions

FRA is revising the definition of ''Tier II'' to conform the maximum authorized operating speed of Tier II passenger equipment in this section (150 mph) with the maximum authorized operating speed of Tier II equipment as specified under § 238.5 of this chapter (160 mph). As a result, the definition of ''Tier II'' under part 229 is revised to mean operating at speeds exceeding 125 mph but not exceeding 160 mph. This was not expressly discussed in the proposed rule; however, this is merely a conforming technical revision and will not impose any additional regulatory requirements or burdens on the regulated industry.

Part 231—Railroad Safety Appliance Standards

Section 231.0 Applicability and Penalties

FRA is revising § 231.0(c) to conform the reference to Tier II maximum authorized speed with the revisions in this final rule. FRA is simply changing the reference to ''150 mph'' to ''160 mph,'' reflecting the changes to the maximum authorized speed of Tier II equipment under this rule. This was not expressly discussed in the proposed rule; however, this is merely a conforming technical revision and will not impose any additional regulatory requirements or burdens on the regulated industry.

Part 236—Rules, Standards, and Instructions Governing the Installation, Inspection, Maintenance, and Repair of Signal and Train Control Systems, Devices, and Appliances

Subpart I—Positive Train Control Systems

Section 236.1007 Additional Requirements for High-Speed Service

FRA is removing paragraph (d) of this section as it is no longer relevant, and redesignating paragraph (e) as paragraph (d) of this section. FRA described the reasons for removing paragraph (d) of this section in the NPRM, see 81 FR 88006, 88017, and did not receive any comments on or objections to the paragraph's removal. As this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, and FRA is adopting this change as proposed.

Part 238—Passenger Equipment Safety Standards

Subpart A—General

Section 238.5 Definitions

In this section, FRA is revising the definitions of ''glazing, end-facing'' and ''glazing, side-facing,'' and making technical revisions to the definitions of ''Tier II'' and ''train, Tier II passenger'' to reflect the change in the maximum authorized speed of Tier II passenger equipment from 150 mph to 160 mph. FRA is also adding new definitions for ''Associate Administrator,'' ''Tier III,'' ''trainset, Tier I alternative passenger,'' ''trainset, Tier III,'' and ''trainset unit.'' For the reasons discussed below, FRA is placing the definition of ''cab'' in new § 238.702, and not under this section as proposed in the NPRM.

FRA did not receive any comments on or objections to FRA's proposed revisions or additions to the definitions of ''glazing, end-facing,'' ''glazing, side-facing,'' ''Tier II,'' ''train, Tier II passenger,'' ''Associate Administrator,'' ''Tier III,'' ''trainset, Tier I alternative passenger,'' and ''trainset, Tier III'' and those definitions in this final rule are identical to the proposed versions. 81 FR 88006, 88018–88019. Accordingly, the analysis provided for these definitions in the NPRM is not being repeated here, and FRA is adopting these definitions as proposed.

FRA did receive comments, however, on the proposed new definitions of ''cab'' and ''trainset unit.'' APTA submitted comments suggesting revisions to the proposed definitions of ''cab'' and ''trainset unit,'' and to FRA's existing definition of ''trainset, passenger.'' Additionally, APTA, along

with Alstom, suggested adding a definition for ''conventional locomotive.'' Further, APTA, along with TCRR, suggested adding a definition for ''Tier IV system.'' However, as discussed more fully under new § 238.702, below, FRA is placing the definition of ''cab'' under subpart H to clarify the definition's application. Accordingly, FRA's discussion of APTA's comment on the term ''cab'' is in the section-by-section analysis of new § 238.702, below.

In its comment, APTA suggested that FRA amend its existing definition of ''trainset, passenger'' to provide a more robust definition to clarify when the term is used in other sections of the rule (*e.g.,* § 238.705, Dynamic collision scenario). APTA suggested that the term ''trainset'' means: ''a passenger train where all units within the trainset are semi-permanently coupled to operate as a single consist. A Tier I alternative trainset may be equipped with a conventional locomotive at either end that may not be semi-permanently coupled to the adjacent unit of the trainset.'' APTA reasoned that the specific requirements proposed by the ETF for a Tier III trainset are based on the assumption that all units within the trainset are semi-permanently coupled together, such that units of the trainset can only be coupled or uncoupled at a maintenance facility or other location where personnel can safely get under or between units. Additionally, APTA commented that, because revenue operations can only be conducted using a complete trainset, the collision scenario defined in § 238.705 is based on the operation of a complete trainset, and mentioned that the specific requirements pertaining to safety appliances for Tier III trainsets are also based on the assumption that all units within a trainset are semi-permanently coupled. Further, APTA proposed allowing a passenger trainset, as it would define the term, to be equipped with an automatic coupler in the middle of the trainset configuration so it could be more easily disconnected in a maintenance facility, noting that for such configurations, the requirements of § 238.705(a) would apply to the complete trainset as operated in revenue service. At this time, FRA is not inclined to amend its current definitions of ''trainset, passenger'' or ''train, passenger,'' and is declining to adopt APTA's proposed definition of ''trainset.'' The definition of passenger trainset in § 238.5 applies to all tiers of passenger equipment under part 238. Specifying that trainsets, generally, are all semi-permanently coupled together places too broad a restriction on the method or manner for connecting individual trainset units. However, in this final rule, new § 238.705(a)(6) does include a reference to an ''integrated trainset'' as defined in new § 238.702, to clarify which initial velocity applies to a given trainset. Moreover, FRA recognizes APTA's concern about allowing for an automatic coupler in the middle of a semi-permanently coupled trainset, but believes no change is needed. FRA makes clear that the rule does not preclude the use of automatic coupler arrangements within the consist of a semi-permanently coupled Tier III trainset to facilitate maintenance within a shop facility, provided the coupler arrangements are not used for switching or other operational purposes outside of the protected maintenance environment envisioned by the rule. Of course, if a coupling between Tier III vehicles is not intended to be semi-permanent in nature, then other requirements apply, such as those governing safety appliances.

APTA also recommended clarifying the definition of ''trainset unit,'' which FRA proposed to mean a trainset segment located between connecting arrangements (articulations). In the NPRM, FRA explained this definition would clarify that the proposed requirements may apply to individual vehicles within a trainset consist, but not necessarily to the trainset as a whole. However, in its comment, APTA suggested restating the definition to mean ''any car within a trainset that is semi-permanently coupled to an adjacent car within the trainset.'' FRA is adopting its proposed definition of ''trainset unit'' in the final rule, not APTA's. APTA's suggested definition would be too narrow because, to be considered a trainset unit, a vehicle would require semi-permanent coupling to an adjacent unit. Yet, FRA intends the definition to apply to all tiers of passenger equipment, and therefore not require all configurations of trainsets to be semi-permanently coupled. FRA believes the definition addresses the essential elements constituting a trainset unit without being too specific.

In their comments, both APTA and Alstom requested FRA add a definition of ''conventional locomotive.'' APTA recommended the rule define ''conventional locomotive'' to mean ''a piece of on-track rail equipment with one or more control stands designed to transport a Tier I alternative compliant passenger trainset and which meets the crashworthiness requirements defined in § 229.205 [of this chapter] and the design requirements contained in § 229.206 [of this chapter].'' APTA stated that inclusion of such a definition would provide greater clarity with respect to application of the dynamic collision scenarios under § 238.705. As discussed below under § 238.705, APTA raised concern that because a conventional locomotive will not be used in Tier III service, requiring use of a conventional locomotive for a collision scenario under Tier III requirements would introduce confusion as to which is the correct collision scenario to apply. Alstom, in its comment, indicated that such a definition of ''conventional locomotive'' would clarify it is Tier I equipment governed by 49 CFR part 229 and that the front vehicle of a Tier III Trainset could therefore not be a conventional locomotive. However, FRA is not adding a definition of ''conventional locomotive'' to this § 238.5 of the final rule. APTA's proposed definition would be too narrowly limited to a locomotive used to move Tier I alternative equipment under appendix G to this part. Instead, FRA believes it is more appropriate to more fully explain under § 238.705, below, FRA's intent on how the two dynamic collision scenarios should be applied. As noted above, FRA is adding the term ''integrated trainset'' to § 238.705 to address any confusion about which initial velocity applies to a given trainset.

As mentioned above in the Discussion of Comments and Conclusions, section IV, APTA and TCRR recommended that FRA include in the final rule a definition of ''Tier IV system.'' According to both APTA and TCRR, a ''Tier IV system would mean ''any passenger rail or ground transportation system that operates on an exclusive right-of-way without grade crossings and is governed by a technology-specific rule of particular applicability, or other regulatory means.'' Although amenable to undertaking the development of such a definition, FRA is not accepting APTA's and TCRR's recommendations to include a definition of a Tier IV system in this final rule. Adding such a broad-ranging definition is beyond the intended scope of this rulemaking at this final rule stage.

Section 238.21 Special Approval Procedure

In commenting on this section in the NPRM, Alstom suggested that a reference to Tier III equipment be added in paragraph (a) where there is currently a reference to Tier II. Alstom noted that paragraph (a) includes a cross-reference to § 238.505, which governs approvals for Tier II ITM programs. While FRA agrees that a change to this paragraph will be warranted in the future, doing so

in this rulemaking is premature as there is no equivalent section to reference for Tier III equipment. However, in the interim, FRA will work with any proposed Tier III operation to ensure that the specific ITM program sufficiently addresses the inspection, testing, and maintenance of all safety-critical features of a Tier III trainset.

FRA is revising paragraphs (c)(2) and (d)(2) of this section, as proposed in the NPRM. FRA did not receive any comments on these technical changes. As these paragraphs are identical to those FRA proposed in the NPRM, please see the NPRM for an analysis of the changes, 81 FR 88006, 88050, as it is not being repeated here.

Subpart B—Safety Planning and General Requirements

Section 238.111 Pre-Revenue Service Acceptance Testing Plan

This section contains requirements for pre-revenue service testing of passenger equipment. As proposed in the NPRM, FRA is amending paragraphs (b)(2), (4), (5), (7), and (c) of this section to require railroads to obtain FRA approval before using Tier III passenger equipment that either has not been used in revenue service in the U.S., or has been used in revenue service in the U.S. and is scheduled for a major upgrade or introduction of new technology that affects a safety system on such equipment. The explicit inclusion of a Tier III notification and approval process is consistent with FRA's approach to the implementation of high-speed rail technology. It also provides a formal mechanism for FRA to ensure all required elements of this part are satisfactorily addressed and documented.

In commenting on the NPRM, APTA stated that FRA should separate out from this section issues related to FRA approval of the design of Tier III equipment. APTA therefore suggested that FRA add a new § 238.110, titled ''Pre-revenue qualification plan,'' to require a plan addressing all documents required by subpart H to be submitted for review and approval for Tier III equipment.'' According to APTA, new § 238.110 would contain the requirements of Tier III equipment design that FRA would need to review and approve before Tier III equipment could operate in revenue service. As discussed above under proposed subpart J and the Safe Operation Plan for Tier III Passenger Equipment, the creation of this new section ties into APTA's comment recommending excluding from this final rule the proposed references to a Tier III Safe Operation Plan. (Please see the discussion above, under proposed subpart J, for FRA's response concerning removal of the Tier III Safe Operation Plan.)

FRA recognizes that § 238.111 will need some further revision as new Tier III equipment requirements are established. However, APTA's request to adopt a new § 238.110 exceeds the intended scope of this current rulemaking proceeding.

Subpart C—Specific Requirements for Tier I Passenger Equipment

Section 238.201 Scope/Alternative Compliance

This section sets out the scope of subpart C, which contains specific requirements for Tier I passenger equipment, and also provides compliance alternatives for the use of Tier I passenger equipment. In its comments on the NPRM, APTA agreed with FRA's proposal to amend this section to allow Tier I equipment to comply with alternative crashworthiness and occupant protection requirements in appendix G to this part, instead of certain requirements under subpart C (§§ 238.203, 238.205, 238.207, 238.209(a), 238.211, 238.213, and 238.219). APTA also urged that efforts be undertaken to complete and reach consensus on a separate guidance document for demonstrating the crashworthiness of passenger rail equipment, to assist with the implementation of this rule. FRA is working on generating such a document, as FRA recognizes the importance of providing guidance on the proper application of the alternative crashworthiness and occupant protection requirements of appendix G to this part.

FRA did not receive any additional comments on the proposed revisions to this section as described in the NPRM, 81 FR 88006, 88019–88020, and FRA is adopting this section as proposed. Accordingly, as this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here.

Sections 238.203, 238.205, 238.207, 238.209, 238.211, 238.213, and 238.219

These sections contain structural and equipment protection requirements for Tier I passenger equipment. FRA did not receive any comments on the proposed revisions to these sections as described in the NPRM, 81 FR 88006, 88020, to reflect the addition of alternative standards in appendix G to this part for Tier I trainsets. As these sections of the final rule are identical to the proposed versions, FRA is adopting them as proposed and the analysis provided in the NPRM for each section is not being repeated here.

Subpart E—Specific Requirements for Tier II Passenger Equipment

Section 238.401 Scope

As discussed in the NPRM, FRA is revising this section to increase the maximum allowable speed for Tier II passenger equipment from 150 mph to 160 mph. This change is consistent with FRA's March 13, 2013, final rule amending and clarifying the Track Safety Standards, which affirmed that the maximum allowable speed on Class 8 track is 160 mph. *See* 78 FR 16052. Further, this change makes the speed range for Tier II passenger equipment consistent with that for Class 8 track in the Track Safety Standards. As specified in § 213.307 of this chapter, Class 8 track encompasses the speed range above 125 mph up to 160 mph—now the same speed range for Tier II passenger equipment. Nonetheless, FRA makes clear this change only increases the maximum operating speed to 160 mph. FRA approval to operate at 160 mph is still needed as this part and other FRA safety regulations require.

In commenting on the NPRM, APTA expressed its support for this change and harmonizing the Track Safety Standards and Passenger Equipment Safety Standards. Separately, APTA stated that it might be appropriate to reexamine Tier II requirements in the future because they were developed prior to the congressional mandate to implement PTC. APTA added that such a reexamination should take into consideration the incident and accident data since the introduction of Amtrak's Acela Express trainsets, along with the corresponding risks associated with future operations and anticipated Northeast Corridor upgrades.

FRA agrees with APTA that if it becomes necessary to reexamine Tier II requirements, it would be appropriate, as always, to consider all relevant safety data available. However, FRA makes clear that the mandate to implement PTC should not be viewed as a replacement for crashworthiness and occupant protection requirements but as a complementary safety measure. Indeed, around the time part 238 was originally published, FRA issued an order of particular applicability for use of the Advanced Civil Speed Enforcement System, a type of PTC system, on Amtrak's Northeast Corridor to support safe train operations at higher speeds. *See* 63 FR 39343 (Jul. 22, 1998)

and subsequent amendments thereto. Moreover, as discussed in the NPRM and in this final rule under § 238.705, not all accidents are PTC-preventable, such as collisions with trespassing highway equipment at grade crossings or with other rolling stock (freight or passenger equipment) during manual operations at speeds 20 mph or below. Accordingly, FRA does not intend to amend the Tier II occupant protection and crashworthiness requirements simply because PTC is installed on the equipment.

FRA did not receive any comments objecting to the revision to this section as described in the NPRM. 81 FR 88006, 88020. As this portion of the final rule is identical to the proposed version, the complete analysis provided in the NPRM is not being repeated here.

Subpart F—Inspection, Testing, and Maintenance Requirements for Tier II Passenger Equipment

Section 238.501 Scope

FRA is revising this section to increase the maximum allowable speed for Tier II passenger equipment from 150 mph to 160 mph. FRA did not receive any comments on the proposed revision to this section as described in the NPRM, 81 FR 88006, 88021, and FRA is adopting it as proposed. Please see the discussion of § 238.401 for further information on this speed change.

Subpart H—Specific Requirements for Tier III Passenger Equipment

This subpart contains specific requirements for Tier III passenger equipment. Many of the requirements under this subpart consider Tier III passenger equipment in terms of an integrated trainset, as that term is now defined under § 238.702, particularly for purposes of crashworthiness and occupant protection requirements. This rule presumes that Tier III trainsets will consist of semi-permanently coupled, articulated, or otherwise ''fixed'' configurations, that are not intended to operate normally as individual vehicles, or in mixed consists (with equipment of another design or operational tier).

The requirements in this subpart are organized into subject areas based on their general applicability: Trainset structure, window glazing, brake systems, interior fittings and surfaces, emergency systems, and cab equipment. FRA intends that the requirements be applied in a manner that is performance-based and technology-neutral, where possible. FRA notes that it intends for certain sections of this subpart to be applied as an integrated set of alternative crashworthiness and occupant protection performance requirements for Tier I passenger equipment as delineated in appendix G to this part. FRA considers this set of requirements to provide an equivalent level of safety to its counterpart set of Tier I requirements in subpart C of this part. As explained in greater detail in the discussion of appendix G below, the rule clarifies which specific Tier III crashworthiness and occupant protection performance requirement should be applied as an alternative set of Tier I counterpart requirements. Specifically, FRA makes clear that if alternative Tier I compliance is sought under appendix G, then all the requirements in appendix G must be met so the integrity of the alternative requirements is maintained.

Section 238.701 Scope

This section sets out the scope of new subpart H. Subpart H contains specific requirements for railroad passenger equipment operating in a shared right-of-way at speeds not exceeding 125 mph, and in an exclusive right-of-way without grade crossings at speeds exceeding 125 mph but not exceeding 220 mph. FRA did not receive any comments on the exclusion of grade crossings or the 125-mph speed limit when grade crossings are present within the right-of-way, or on whether FRA should explicitly apply the 125-mph speed limit only to track located at or near each grade crossing within an exclusive right-of-way. As stated in the NPRM, FRA believes that in most cases new, exclusive rights-of-way designed for Tier III operations will be constructed without highway grade crossings, see 81 FR 88006, 88021. However, in the situation where exclusive rights-of-way include highway grade crossings, but may have long stretches of track without a grade crossing, FRA would expect appropriate operational safeguards to be in place to prevent trainsets from traversing highway grade crossings at speeds exceeding 125 mph. In fact, FRA would expect those operations that include grade crossings in their exclusive rights-of-way to also comply with the requirements of § 213.347 of this chapter.

Section 213.347(a) of this chapter prohibits any grade crossings on Class 8 or 9 track. Whereas Class 8 track is track with an operational speed range from above 125 mph not exceeding 160 mph, Class 9 track is track with an operational speed range from above 160 mph not exceeding 220 mph. Further, § 213.347(b) of this chapter requires a track owner of Class 7 track (track with an operational speed range from above 110 mph not exceeding 125 mph) to submit for FRA's approval a complete description of the proposed warning/barrier system to address the protection of highway traffic and high-speed trains if the track will include highway grade crossings. Section 213.347(b) of this chapter prohibits operations on Class 7 track unless such an FRA-approved warning barrier system is in place and functioning as intended.

Separately, FRA received comments on its proposal to allow passenger seating in the leading unit of a Tier III trainset provided safety issues associated with passengers occupying the leading unit are addressed and mitigated through a comprehensive Tier III Safe Operation Plan. (See the discussion of proposed subpart J and the Safe Operation Plan for Tier III Passenger Equipment, under Discussion of Comments and Conclusions, section IV, above.) APTA stated that addressing safety concerns in a Tier III Safe Operation Plan is unnecessary because those safety concerns are already addressed through other regulatory means. APTA maintained that when Tier III equipment is operating at speeds not exceeding 125 mph, the crashworthiness and occupant protection requirements provide an equivalent level of safety to that of Tier I equipment and sufficient protection is already afforded passengers occupying leading units of Tier III trainsets. Additionally, APTA suggested that when operating above 125 mph, the right-of-way barrier plan required under § 213.361 of this chapter and the HSR–125 plan required under § 236.1007 of this chapter address any additional safety concerns for passengers occupying the leading units of Tier III trainsets, as these two sections guard against unauthorized intrusions into the right-of-way. Accordingly, APTA believed that conducting an additional, comprehensive analysis for the Tier III Safe Operation Plan would be redundant.

Alstom's comment on this section mirrored APTA's comment in substance. Alstom also suggested that the safety considerations that FRA initially sought to address in the Tier III Safe Operation Plan are adequately addressed just as APTA outlined in its comment.

As explained under Discussion of Comments and Conclusions, section IV, above, this section does not refer to a Tier III Safe Operation Plan. This final rule does not require railroads to complete a comprehensive safety analysis specifically addressing and mitigating all safety conditions

associated with passengers occupying the lead unit of a Tier III trainset. Instead, FRA's regulations continue to require, before passengers can occupy the lead unit of a Tier III trainset, that railroads seeking to do so namely have an approved right-of-way plan that complies with the requirements of § 213.361 of this chapter, have an approved PTC Safety Plan that complies with § 236.1007(c) of this chapter, and, as appropriate, comply with § 213.347 of this chapter. These requirements should not place any additional regulatory burden on a Tier III operation as these are all existing regulatory requirements. However, FRA does make clear that prior to any train operation in which passengers other than assigned crew members (*i.e.,* engineers and conductors) occupy the lead unit of a Tier III trainset, the above requirements must be met, regardless of whether operating in revenue service (*i.e.,* whether or not the passengers have paid a fare to ride). Additionally, if a railroad does identify safety concerns involving passengers occupying the lead unit of a Tier III trainset, FRA expects the railroad to properly and adequately address the concerns. Similarly, FRA reserves the right to ensure that the railroad properly and adequately addresses safety concerns involving passengers occupying the lead unit of a Tier III trainset, if FRA's inspection of a Tier III railroad operation identifies such safety concerns.

Finally, as noted earlier, APTA suggested that FRA create a new section, § 238.110, to address compliance review and approval with the requirements of this subpart H. See FRA's discussion of this suggestion under Discussion of Comments and Conclusions, section IV, above.

Section 238.702 Definitions

FRA has added this new section to contain definitions applying specifically to subpart H of this part. This section defines the terms ''cab,'' which was proposed in the NPRM under § 238.5, and ''integrated trainset,'' which is a new term not expressly proposed in the NPRM. FRA determined it will be clearer and more useful to place definitions that are tailored to the application of subpart H in this section, rather than in this part's general definitions section, § 238.5.

In its comments on the proposed definition of ''cab,'' APTA recommended FRA remove the proposed statement that the term ''cab'' includes a locomotive cab for the purposes of subpart H. According to APTA, the Tier III trainsets subpart H addresses do not have locomotive cabs. APTA also commented that any analysis for a Tier I alternatively compliant trainset as governed by appendix G cannot include an analysis of the cab of a conventional locomotive because the collision model used for that analysis is insufficient. APTA suggested instead to revise the proposed definition of ''cab'' to mean ''for the purposes of subpart H of this part, a compartment or space in a trainset designed to be occupied by the engineer and contain an operating console from which the engineer exercises control over the trainset.'' When discussed at the May 2017 ETF meeting, APTA expanded on its comment saying that if the definition were to remain as proposed, there would need to be a way to differentiate between when the term ''cab'' applies to a Tier III trainset versus a conventional locomotive cab. APTA stated this is crucial when applying the dynamic collision scenario under § 238.705 because (as discussed more comprehensively below) a Tier III trainset cannot be led by a conventional North American locomotive in its intended service.

FRA recognizes APTA's underlying concern with the proposed definition of ''cab.'' FRA has therefore defined the term in this section of the final rule to better clarify how the term is applied to Tier III equipment, and by extension of appendix G to this part, Tier I alternative equipment. Accordingly, the term ''cab'' means a compartment or space within a trainset that is designed to be occupied by an engineer and contain an operating console for exercising control over the trainset. As the definition is contained in this new section, which applies specifically to subpart H, there is no need to add language to the definition expressly limiting its application.

In addition, as fully discussed below, FRA has included the term ''integrated trainset'' in § 238.705 and is defining that term in this § 238.702. FRA believes that any confusion over which initial velocity applies to a given trainset undergoing evaluation in the dynamic collision scenario in § 238.705 is reconciled with the new term ''integrated trainset.'' The term ''integrated trainset'' is defined as a passenger trainset in which all units of the trainset are designed to operate as an integrated consist to achieve its structural crashworthiness performance. FRA intends the term ''integrated trainset'' to mean that each individual vehicle comprising the trainset is interdependent structurally with each other, specifically with respect to the collision load path and how the collision loads are designed to be resolved.

Trainset Structure

Section 238.703 Quasi-Static Compression Load Requirements

This section contains the quasi-static compression load requirements for Tier III equipment. This section also requires compliance with § 238.705 to demonstrate sufficient occupied volume integrity (OVI). The purpose of applying both requirements is to ensure the integrity of the occupied volume during a collision or other accident. Integrity of the occupied volume is a fundamental requirement of crashworthiness—the primary goal of which is preservation of space to protect occupants during an accident. Additionally, a strong occupied volume serves as the foundation for other crashworthiness features such as CEM components. And although the language of this section references only Tier III trainsets, the requirements of this section may also be applied to Tier I trainsets through the application of appendix G, in the alternative to the requirements of 49 CFR 238.203, Static end strength. Tier I passenger equipment designed to alternative crashworthiness standards may demonstrate an appropriate level of crashworthiness by complying with the quasi-static compression load requirements proposed in § 238.703(b).

FRA received one comment on this section. The commenter, Alstom, stated that the methodology necessary to properly apply the collision load along the collision load path was not included in the proposal, and suggested FRA supply that methodology in some form of compliance manual or document. FRA does agree with Alstom that providing guidance on how to properly apply the requirements of this section would be beneficial to the regulated community. However, to remain technology neutral, FRA did not propose a specific methodology in the rule text. FRA understands there may be different methodologies that are equivalent, and thus putting one in the regulation over another could unintentionally limit the technology employed. FRA intends to address this issue in developing a guidance document, as discussed above.

FRA did not receive any other comments on the requirements in this section as described in the NPRM, 81 FR 88006, 88021–88023, and FRA is adopting this section as proposed. Because this portion of the final rule is identical to the proposed version, the complete analysis provided in the NPRM is not being repeated here.

Section 238.705 Dynamic Collision Scenario

As discussed in the NPRM, this section contains the dynamic collision scenario analysis requirements as the second part of the OVI evaluation of a Tier III passenger trainset, in conjunction with § 238.703. Because PTC technology does not protect against all possible collision scenarios, such as collisions with trespassing highway equipment at grade crossings or with other rolling stock (freight or passenger equipment) during manual operations at 20 mph or below, compliance with this requirement is necessary to preserve the occupied volume, to protect all occupants on the trainset.

As mentioned in the discussion of § 238.703, each vehicle in the trainset needs to demonstrate it meets both the OVI requirements in paragraph (b) of that section and the dynamic collision scenario requirements in paragraph (b) of this section. Further, as provided in § 238.703, and as outlined in appendix G, a Tier I passenger trainset designed to alternative crashworthiness standards may comply with this section instead of the requirements applicable to Tier I passenger trainsets in § 238.203.

In combination with the quasi-static compression load requirements in § 238.703, the purpose of this dynamic collision scenario requirement is to ensure that survivable space for the passengers and crew is preserved in up to moderately severe accident conditions (*i.e.,* conditions comparable to a head-on collision at speeds of 20 to 25 mph, depending on the type of equipment, into a stationary train). This requirement also provides a baseline level of protection for scenarios that may be more severe, but less predictable with respect to loading conditions and historical accident data. Although the dynamic collision scenario is conducted at the trainset level, the requirements described in this section are evaluated at the level of the trainset's individual vehicles so no vehicle in the trainset may exceed the parameters outlined in paragraph (b) as a result of the dynamic collision scenario.

Paragraph (a) outlines the required conditions under which a dynamic collision scenario is performed. Generally, the collision scenario requires a dynamic impact to be simulated between an initially-moving trainset and an initially-standing train. The initially-moving trainset is the trainset undergoing evaluation, either Tier III equipment or, as provided in appendix G, Tier I equipment designed to alternative crashworthiness standards. The initially-standing train is a locomotive-led consist of five conventionally-designed passenger cars. The conventionally-designed passenger cars have a prescribed weight and force-versus-displacement characteristic.[15] The pass/fail criteria for the scenario determine whether there is sufficient preservation of occupied volume for passengers and crew in the trainset undergoing evaluation.

FRA expects the collision scenario simulation to be executed for an impact duration sufficient to capture the most severe portion of the collision event. The actual amount of impact time required to simulate the collision sufficiently will vary based upon the characteristics of the trainset undergoing evaluation. Typically, the collision scenario will be executed until all the equipment, including the initially-standing train and initially-moving trainset, is moving in the same direction at approximately the same velocity. If all the equipment is moving together at approximately the same speed, no further vehicle-to-vehicle impacts will occur, and the simulation will then have been executed for a sufficient duration to capture the most severe decelerations.

There are various types of analyses that may be used to evaluate the collision scenario requirements. These analyses include fully-detailed FE models, lumped-parameter analyses, or a hybrid approach where a combination of detailed FE modeling and lumped-parameter techniques are used within the same simulation. An FEA of the scenario is generally a highly-detailed simulation of the actual trainset geometry. The parts making up the trainset are meshed into a large number of elements, with each element having its own mass, stiffness, and connection properties to the adjacent elements. A lumped parameter analysis represents each car or section of a car within a trainset using a small number of masses and a small number of non-linear springs. At its extreme, each vehicle consists of a single mass and a single spring characteristic. A hybrid approach may utilize an FE mesh to represent some structures (*e.g.,* CEM structures that undergo large deformations) and lumped-parameter representations of other structures (*e.g.,* vehicles far from the impacting interface that experience little deformation). Any of the three types of analyses is capable of developing the information needed to verify a trainset's ability to meet the requirements of the collision scenario. Additionally, because the centerlines of the initially-moving trainset and initially-standing train are aligned with one another during this scenario, a half-symmetric model may be used to represent the colliding vehicles, as appropriate.

FRA received comments from APTA recommending revisions to several paragraphs of this section in the NPRM. In its comments on the NPRM, APTA recommended that FRA replace the references made to ''train'' in paragraphs (a)(1)–(3), (6), and (8), and replace them with the term ''trainset,'' to clarify the application of the collision scenario under paragraph (a) of this section. APTA proposed that the term trainset be defined to mean a passenger train where all units within the trainset are semi-permanently coupled to operate as a single consist. As stated under the discussion of § 238.5, FRA has not adopted APTA's proposal definition of ''trainset.'' However, FRA does agree that reference to a trainset is more appropriate than to a ''train'' in this section. Accordingly, the above-referenced paragraphs of paragraph (a) use the term ''trainset,'' instead of ''train,'' and FRA intends the term ''trainset'' to mean either a Tier I alternative or Tier III trainset, as those terms are defined in § 238.5. However, with reference to the initially-standing train, as FRA envisions it being reflective of a conventional Tier I passenger train, FRA is using the term ''train'' for clarity. Although not specifically requested by APTA, paragraphs (a)(4) and (9) use the term ''trainset'' in conformance with these changes.

In commenting on the NPRM, APTA recommended that paragraph (a)(3) be placed in appendix G to part 238, consistent with its other comments that requirements for conventional locomotive led equipment are not appropriate in subpart H because Tier III equipment will not utilize conventional locomotive power. APTA also suggested that the text adopt APTA's proposed definition of ''trainset'' instead of ''train,'' as proposed. Paragraph (a)(3) of this section, as proposed in the NPRM, stated that if the trainset is intended for use in push-pull service, then both the locomotive-led and cab-car-led configurations would require separate evaluation. This proposal was intended to ensure sufficient OVI for all occupied spaces in the trainset regardless of whether led by a cab car or a conventional locomotive.

FRA's discussion of the use of the term ''conventional locomotive'' in paragraph (a)(6) of this section applies

[15] Appropriate weights and force-versus-displacement characteristics for the conventionally-designed passenger cars can be found in the Technical Criteria and Procedures Report.

here, in response to APTA's concern, as discussed below. In the final rule, this paragraph (a)(3) omits specific references to ''locomotive'' or ''cab car'' and requires that if the initially-moving trainset is intended for use in push-pull service, then, as applicable, each configuration of leading vehicle shall be evaluated separately. By requiring that each lead vehicle be evaluated separately, FRA intends to capture situations where the lead vehicles of a push-pull operation could be two different styles of vehicle that could potentially have different designs and structural characteristics, and thus have different crashworthiness and occupant protection capabilities. This paragraph eliminates any reference to a specific technology and only requires separate evaluation if the lead vehicles are different. FRA recognizes that some push-pull operations do not necessarily require a locomotive-like vehicle on one end with a cab car-like vehicle on the other. But when the two vehicles are different, in design or structural make-up, then the crashworthiness and occupant protection capabilities of each vehicle must be evaluated.

In its comments on this section, Alstom also raised concern about how to implement the force-versus-crush requirements in proposed paragraph (a)(4)(ii) and Table 1 to this section. Proposed paragraph (a)(4)(ii) stated that the rigid locomotive and each passenger coach in the initially-standing train crush in response to applied force as specified in Table 1, which in turn provided the non-linear, force-versus-crush relationships for the passenger cars and locomotive comprising the initially-standing train. In particular, Alstom found it unclear whether the paragraph made it necessary to combine characteristics at ''inter-trailers,'' and, if so, how to do so. Alstom therefore suggested that the force-crush characteristics to be used at each interface between vehicles be included in this paragraph instead of Table 1.

FRA makes clear that the force-crush characteristics described in Table 1 are intended for use as inputs to a lumped-parameter simulation model of a train-to-train collision. The data in Table 1 describe the resulting force when the equipment moves into a rigid fixed barrier. In the initial position, when the crush is 0 inches, the passenger coach is just touching the barrier and the force is also 0 lbf. The length of the coach is reduced as the coach moves towards the barrier and crushes. When the coach has crushed by 3 inches, the force has increased linearly to 80,000 lbf. When the coach has crushed by 6 inches, the force again increases linearly to 250,000 lbf, from 80,000 lbf. For the rigid locomotive, the force is 0 lbf when the crush is 0 inches and the rigid locomotive is just touching the barrier. After 2.5 inches of crush, the force increases linearly to 100,000 lbf. When the rigid locomotive has crushed by 5 inches, the force again increases linearly to 2,500,000 lbf, from 100,000 lbf.

Depending on the details of the software used to implement the lumped-parameter model, the data in Table 1 may need to be re-formatted. Some software may allow the data to be input simply as it is presented in Table 1. Other software may require coach-to-coach force crush characteristics for input. For coach-to-coach crush, the crush distances simply double for the corresponding force. Accordingly, 6 inches of crush between coaches are required to reach 80,000 lbf, and 12 inches of crush are required to reach 2,500,000 lbf. For rigid locomotive-to-coach crush, some calculations are required. At 80,000 lbf between the rigid locomotive and coach, the rigid locomotive has crushed by 2 inches, while the coach has crushed by 3 inches. The rigid locomotive-to-coach crush is then 5 inches when there is 80,000 lbf between the rigid locomotive and coach. At 100,000 lbf between the rigid locomotive and coach, the rigid locomotive has crushed by 2.5 inches and the coach has crushed by 3.35 inches. The rigid locomotive-to-coach crush is 5.85 inches at 100,000 lbf. At 2,500,000 lbf between the rigid locomotive and coach, the rigid locomotive has crushed by 5 inches and the coach has crushed by 6 inches. The rigid locomotive-to-coach crush is 11 inches at 2,500,000 lbf.

Calculations may be necessary to determine the force-crush characteristic between the rigid locomotive described in Table 1 and the new equipment under evaluation. The details of such calculations will likely depend on the software modeling choices. One possibility, of many, is to calculate the force-crush response of the new equipment with a rigid fixed barrier, and use those results in combination with the rigid locomotive data in Table 1. The force-crush characteristic for the rigid locomotive to the new equipment may then be calculated in a manner similar to the force crush characteristic for the rigid locomotive to the coaches.

Most notably, APTA recommended revising paragraph (a)(6), which specifically describes the initial velocities to be assigned to the initially-moving trainset in the dynamic collision scenario. FRA makes clear that, although the collision scenario in paragraph (a)(6) references ''initial velocities'' for the scenario, FRA expects that the actual velocity at the colliding interface be the same as the initial velocity, as generally models do not account for loss of velocity. However, if a model includes loss of velocity due to friction, or other velocity-reducing forces, FRA would expect the initial velocity to be increased so that the collision velocity remains either 20 mph or 25 mph, depending on the equipment undergoing evaluation. As proposed in the NPRM, if the initially-moving trainset were led by a cab car or an MU locomotive, its initial velocity would be 20 mph; if the initially-moving trainset were led by a conventional locomotive, its initial velocity would be 25 mph. These speeds were chosen based upon estimates of the upper limit of the ability of conventionally-designed Tier I equipment to maintain its occupied volume in a similar collision scenario.

APTA commented that, although it is probable for a Tier I alternative trainset, it is not possible for a Tier III trainset to be led by a conventional North American locomotive. APTA stated that a Tier III trainset could never meet its performance capabilities with a conventional locomotive on the leading and trailing ends, because the end units must be low-profile, aerodynamic designs that are an integral part of the trainset design. APTA therefore suggested that the portion of the rule text involving an initially-moving consist led by a conventional locomotive be placed in appendix G to this part and not contained in this section.

Alstom also provided comments on paragraph (a)(6) of this section. Specifically, Alstom sought clarification of the application of the 20-mph and 25-mph initial velocities. Alstom did not believe having two initial velocities makes sense and suggested there should instead be only one initial velocity applicable to all equipment—an initial velocity for all Tier III trainsets.

FRA carefully considered both APTA's and Alstom's comments on this paragraph. FRA recognizes the importance of ensuring that the intent of the section's application is clearly understood so that equipment designed to the Tier III crashworthiness and occupant protection requirements, or the Tier I alternative requirements, properly preserves the occupied volume in the event of a collision. As discussed above, the collision scenario speeds were chosen based upon estimates of the upper limit of the ability of conventionally-designed Tier I equipment to maintain its occupied volume in a similar collision scenario. FRA did not intend inclusion of two

collision scenario speeds to create ambiguity but rather to clarify and refine the application of this paragraph depending on the type of equipment used. Nonetheless, FRA recognizes that use of the term ''conventional locomotive'' for purposes of applying the dynamic collision scenario requirements could cause confusion. FRA did not intend for the reference to a ''conventional locomotive'' to necessarily mean a conventional North American locomotive. Instead, FRA intended the reference to refer more generally to the use of a rigid locomotive, especially a surrogate model of a rigid locomotive when the leading unit is unknown. This is why FRA included in the proposed rule text a rigid locomotive model, as described and depicted in appendix H to this part, Rigid locomotive design computer model input data and geometrical depiction. Accordingly, FRA has holistically revised this section from that proposed in the NPRM to remove the term ''conventional locomotive'' and replace it with the term ''rigid locomotive,'' referencing the rigid locomotive model in appendix H.

FRA notes that it also considered drafting the regulatory text so that the 20-mph initial velocity would apply to a trainset led by a vehicle designed to be occupied by passengers, and the 25-mph initial velocity would apply to a trainset led by equipment not designed to be occupied by passengers. When this issue was discussed at the May 2017 ETF meeting, the ETF members rejected this approach. Simply referencing a locomotive not designed to be occupied by passengers instead of a conventional locomotive did not fully resolve the issue, because of concern that a Tier III trainset may not be powered by a stand-alone power unit but rather through an integrated system in which powered axles are distributed throughout the trainset. Additionally, a question arose whether a control cab in the lead unit of such an integrated and powered trainset design made that lead unit an MU, further clouding which initial velocity would apply. Moreover, to the extent passengers do not occupy the lead unit in such a trainset, there would be a large mass in front of passenger-occupied units that allows for more absorption of energy not being transferred to the passenger-occupied units, and the ETF raised concern that the lead unit in such a trainset not be subjected to more stringent requirements.

In discussing how best to clarify the application of the requirements of this paragraph, ETF industry representatives mentioned that the requirements, when developed for the Technical Criteria and Procedures Report, were intended to apply to integrated trainsets, not trainsets led by conventional North American locomotives. Consistent with the comments APTA and Alstom submitted, ETF industry representatives suggested applying the 20-mph initial velocity to Tier III trainsets in this section, and applying the 25-mph initial velocity to Tier I alternative trainsets in appendix G to this part. ETF labor representatives noted the original consensus product of the ETF and cautioned against re-drafting consensus language. After a healthy discussion and to remain technology neutral, FRA proposed to the ETF the concept of using the term ''integrated trainset'' for determining which initial velocity applies. If the design of the trainset was integrated from a structural and crashworthiness perspective, with all vehicles inclusive of the leading unit designed to work together in a collision scenario, then the 20-mph initial velocity would apply. For all other configurations not considered ''integrated,'' regardless of the equipment's tier and what type of unit leads the trainset, the 25-mph initial velocity would apply. Such an approach would take into account instances when the lead unit of a Tier III trainset and its passenger coaches would be manufactured by different companies. Further, because properly testing the crashworthiness and occupant protection capabilities of the passenger coaches must involve some known characteristics of the vehicle leading the trainset, this section would consider such a trainset a non-integrated trainset led by a surrogate for the lead unit, and reflect that the collision load paths of the lead unit and the coach cars are not structurally interdependent.

Accordingly, in the final rule, FRA has not adopted the proposed references to cab cars, or MU or conventional locomotives. Rather, paragraph (a)(6) of this section requires the initially-moving trainset to have an initial velocity of 20 mph if it is an integrated trainset, as that term is now defined under § 238.702, or an initial velocity of 25 mph when the lead vehicle is not part of the integrated design. By using the term ''integrated trainset,'' FRA intends to remain technology-neutral and not restrict the type of equipment that could potentially lead a Tier III trainset. As long as the entire trainset is designed and built as an integrated trainset, the 20-mph initial velocity applies.

FRA also received comments from APTA concerning paragraph (b) of this section, which contains the crashworthiness and occupant protection performance requirements the individual vehicles in the initially-moving trainset involved in the dynamic collision scenario must meet as described in paragraph (a). Specifically, FRA proposed in paragraph (b)(2) that if the option to use GM/RT2100 is exercised to demonstrate compliance with any of the requirements in §§ 238.733, 238.735, 238.737, or 238.743, then the average longitudinal deceleration of the center of gravity (CG) of each vehicle during the dynamic collision scenario shall not exceed 5g in any 100-millisecond (ms) time period. FRA explained that a plot of the 100-ms average longitudinal deceleration versus time, in which the curve never exceeds 5g, would suffice to demonstrate compliance with paragraph (b)(2). APTA, in its comment, noted that proposed paragraph differed slightly from the consensus agreement. However, APTA expressed its agreement with the proposal if FRA intends the rule to allow the use of a moving window of a 5g average deceleration within 100 ms.

FRA makes clear that the differences between the consensus rule text and the proposed rule text were merely editorial in nature and in no way changed the substantive intent that the average longitudinal deceleration of the CG of each vehicle of the initially-moving trainset during the dynamic collision scenario not exceed 5g in any 100-ms time period. Additionally, FRA disagrees with APTA's characterization of the intent of this section. The average deceleration in any 100-ms period was never intended to be comprised of the most favorable data points during the time period, *e.g.,* selecting only those decelerations that are at or below 5g, to demonstrate compliance. It has always been FRA's intent that a representative data set be used to calculate the average deceleration. However, because FRA recognizes the possibility that this intent may be overlooked, or otherwise not followed, FRA is including text in paragraph (b)(2) specifying that the maximum interval between the data points averaged in the 100-ms time period shall be no greater than 1 ms. This means that each deceleration experienced during each millisecond of the 100-ms period must now be used to calculate the average deceleration under paragraph (b)(2) of this section. FRA believes this provision will help assure that the average taken during the 100-ms time period is based on a sufficient data set, so that there is a high degree of confidence and accuracy supporting the calculated average deceleration.

FRA has otherwise adopted this section as proposed in the NPRM, and the complete analysis provided in the NPRM is not being repeated here.

Section 238.707 Override Protection

This section contains the requirements for analyzing the ability of a Tier III passenger trainset to resist vertical climbing or override at its collision interface locations during a dynamic collision scenario. This section examines the vertical displacement behavior of colliding equipment under an ideal impact scenario where an initially-moving Tier III trainset and an initially-standing train are aligned. This section also prescribes an impact scenario where the interface of the colliding equipment is translated both laterally and vertically by 3 inches to ensure that override is resisted during an impact when the two trains are not perfectly aligned. Evaluating the colliding equipment's ability to resist override in an offset impact condition helps to demonstrate that the override features are robust. As proposed, Tier III passenger trainsets must comply with both paragraphs (a) and (b) of this section.

FRA received comments from Alstom on this section on proposed paragraphs (a)(1)(ii) and (b)(1)(ii). Alstom stated that the direction of the vertical perturbation required in each paragraph was not defined (*i.e.,* whether the perturbation is upwards or downwards). Alstom recommended that the rule specify which direction the initially-moving trainset is to be perturbed, to remove any confusion on how the dynamic collision scenario under § 238.705(a) is applied to properly evaluate the equipment's resistance to override.

FRA agrees with Alstom's comment, and for the reasons discussed below, paragraph (a)(1) in the final rule contains three sets of initial conditions for analyzing the ability of the evaluated trainset to resist vertical climbing or override during a dynamic collision scenario. Paragraph (a)(1) also states these conditions must be applied using the dynamic collision scenario in § 238.705(a). The criteria for evaluating the dynamic collision scenario for each set of initial conditions are provided in paragraph (a)(2), and remain unchanged from the NPRM. Because the same model may be used both to demonstrate compliance with the requirements of § 238.705 and the requirements of paragraphs (a) and (b) of this section, the model must be validated with test data in such a way as to provide confidence in the validity of the results of the collision analyses. In this regard, if the components that experience large deflection or permanent deformation in the analysis described in § 238.705 also experience large deflection or permanent deformation in the analysis described in paragraph (a)(2) of this section, then the same test results may be used to validate the model. If the performance of the components that undergo large deformation in the analysis described in paragraph (a)(2) of this section is not validated with test data as part of the validation of the model used in § 238.705, then additional validation testing must be performed to validate the model being used to demonstrate performance under paragraph (a)(2).

Paragraph (a)(1)(i) describes the first condition to be used in the collision simulation to demonstrate anti-climbing performance, and remains unchanged from the NPRM. This paragraph still provides that all vehicles in both the initially-moving trainset and the initially-standing train consists must be positioned at their nominal running heights with the centerlines of the initially-moving trainset and initially-standing train aligned. Because the centerlines of the colliding vehicles are aligned with one another, a longitudinally half-symmetric model may be used to simulate this collision scenario, as appropriate. FRA intends for this initial condition to represent an ideal collision situation where the colliding vehicles are initially aligned with one another.

As proposed, paragraph (a)(1)(ii) described the second condition to be used in the collision simulation as a 3-inch lateral and 3-inch vertical offset of the interface of the colliding equipment, without defining the direction of the perturbance. It is here where Alstom's comment was focused. FRA notes that implicit in the proposed regulatory text for this paragraph was an assumption that, to demonstrate compliance with this section, a railroad or manufacturer would choose the more unfavorable arrangement (upwards or downwards perturbance) with respect to override (the arrangement most likely to lead to override) to be evaluated. However, FRA recognizes that this assumption was not made clear. Therefore, in the final rule, FRA has provided more detail in paragraph (a)(1)(ii) and included new paragraph (a)(1)(iii). Although FRA is being more prescriptive with respect to the requirements of this section to remove ambiguity on its application, FRA still expects that when a scenario arises where there are multiple arrangements that can be evaluated, the most severe scenario (the scenario most likely to lead to override) will be evaluated and the results used to determine whether compliance with the requirements of this section has been achieved.

Accordingly, paragraph (a)(1)(ii) specifies that the initially-moving trainset must be perturbed 3-inches laterally and 3-inches vertically upwards relative to the initially-standing train. Further, paragraph (a)(1)(iii) requires that the initially-moving trainset must be perturbed 3-inches laterally and 3-inches vertically downwards relative to the initially-standing train. The lateral and vertical offsets still must be applied simultaneously in the same simulation. Evaluating the equipment offset in this manner will demonstrate that the anti-climb features are of a robust design, capable of preventing climbing when the colliding vehicles are not perfectly aligned. Because these simulations require a lateral offset between the initially-standing train and initially-moving trainset, a symmetric boundary condition may not be employed (*i.e.,* the full width of each consist must be modeled).

Paragraph (a)(2) remains unchanged from the NPRM, except for use of the term ''trainset,'' instead of ''train,'' to remain consistent with use of the term in other sections of this final rule. This paragraph explains the pass/fail criteria that must be successfully met to demonstrate a trainset possesses adequate anti-climb features for its colliding interface. The criteria must be met for each set of initial conditions in paragraphs (a)(1)(i)–(iii) for demonstrating appropriate resistance to override between colliding equipment.

Paragraph (b) contains the evaluation methodology for demonstrating the appropriate level of override protection for connected equipment in a Tier III trainset. This paragraph requires examination of the vertical displacement behavior of coupled equipment under an ideal impact scenario where the vehicles within the initially-moving trainset are aligned. It also prescribes an impact scenario where the first coupled interface of the initially-moving trainset is translated both laterally and vertically by 2 inches. Evaluating the connected equipment's ability to resist override in an offset impact condition is necessary to demonstrate the override features are robust and can resist override during an impact where the coupled vehicles are not perfectly aligned.

Paragraph (b)(1) explains the conditions for analyzing the ability of connected equipment to resist vertical climbing or override at the coupled interfaces during a dynamic collision

scenario, using the scenario described in § 238.705(a). Like paragraph (a) of this section, each set of conditions in paragraphs (b)(1)(i)–(iii) must be evaluated independently. Criteria for evaluating the dynamic collision scenario for each set of conditions are in paragraph (b)(2). As noted in the discussion of paragraph (a), because the same model may be used to demonstrate compliance with the requirements of § 238.705 and the requirements of this section, the model must be validated with test data in a way that provides confidence in the validity of the results of the collision analyses. The discussion of model validation in paragraph (a) applies equally to model validation for purposes of paragraph (b).

Paragraph (b)(1)(i) describes the first condition to be used for collision simulation to demonstrate override protection for connected equipment, and remains unchanged from the NPRM. This paragraph provides that all vehicles in both the initially-moving trainset and the initially-standing train consists must be positioned at their nominal running heights, with the centerlines of the initially-moving trainset and initially-standing train aligned. Because the centerlines of the colliding vehicles will be aligned with one another, a longitudinally half-symmetric model may be used to simulate this collision scenario, as appropriate. This initial condition is meant to represent an ideal collision situation where the colliding vehicles are initially aligned with one another.

As proposed, paragraph (b)(1)(ii) described the second condition to be used in the collision simulation as a 2-inch lateral and 2-inch vertical offset of the first connected interface between vehicles in the initially-moving train. As discussed above, Alstom raised concern that the proposed paragraph did not define the direction of the vertical offset. Accordingly, FRA is employing the same approach here as under paragraph (a)(1)(ii) to clarify the direction of the vertical offset and is also including a new paragraph (b)(1)(iii).

In the final rule, paragraph (b)(1)(ii) specifies that the first connected vehicle behind the lead unit of the initially-moving trainset must be perturbed 2-inches laterally and 2-inches vertically upwards, relative to the adjacent vehicle, at the first connected interface. Further, paragraph (b)(1)(iii) requires that the first connected vehicle behind the lead unit of the initially-moving trainset must be perturbed 2-inches laterally and 2-inches vertically downwards, relative to the adjacent vehicle, at the first connected interface. The lateral and vertical offsets must still be applied simultaneously in the same simulation. Evaluating the equipment offset in this manner will demonstrate that the anti-climb features are of a robust design, capable of preventing climbing when the vehicles in the initially-moving trainset are not perfectly aligned. Because these simulations require a lateral offset between the vehicles of the initially-moving consist, a symmetric boundary condition may not be used (*i.e.,* the full width of each consist must be modeled).

Paragraph (b)(2) remains unchanged from the NPRM, except for use of the term ''trainset,'' instead of ''train,'' to remain consistent with use of the term in other sections of this final rule. This paragraph sets out the pass/fail criteria that must be successfully met to demonstrate a Tier III trainset possesses adequate anti-climb features to protect the vehicles connected in the trainset from overriding each other. The criteria must be met for each set of initial conditions provided in paragraphs (b)(1)(i)–(iii) to demonstrate appropriate resistance to override between connected equipment.

Under appendix G to this part, a Tier I alternative passenger trainset may demonstrate an appropriate level of override protection by complying with the requirements of this section instead of the requirements applicable to Tier I passenger train in § 238.205, Anti-climbing mechanism, and § 238.207, Link between coupling mechanism and car body, as proposed. In general, the requirements in this section were developed as an alternative to demonstrating anti-climbing capabilities in § 238.205 and the capability of the link between the coupling mechanism and carbody to resist the loads in current § 238.207. While compliance with both §§ 238.205 and 238.207 requires meeting a set of quasi-static, vertical load cases, the requirements in this section were developed as a dynamic performance standard.

Section 238.709 Fluid Entry Inhibition

This section contains the requirements for fluid entry inhibition for the skin covering the forward-facing end of a Tier III trainset. FRA received one comment on this section from APTA which agreed with the language of this section, noting that compliance with this section can be demonstrated during a design review of the equipment. As this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, see 81 FR 88006, 88026, and FRA is adopting this section as proposed.

Section 238.711 End Structure Integrity of Cab End

This section contains requirements to ensure the structure of cab ends of Tier III trainsets (and Tier I trainsets designed to alternative crashworthiness standards under appendix G) provides a minimum level of protection for the engineer and other cab occupants, equivalent to the collision post and corner post requirements for Tier I equipment in subpart C. FRA did not receive any comments on these requirements and FRA is adopting this section as proposed. Accordingly, as this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, see 81 FR 88006, 88027.

Section 238.713 End Structure Integrity of Non-Cab End

This section contains requirements to ensure the structure of the non-cab ends of Tier III trainsets (and Tier I trainsets designed to alternative crashworthiness standards under appendix G) provides a minimum level of protection for occupants equivalent to that required for Tier I equipment in subpart C. These requirements help ensure the integrity of the components that make up any non-cab end of a passenger trainset unit. FRA did not receive any comments on these requirements and FRA is adopting this section as proposed. Accordingly, as this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, see 81 FR 88006, 88027.

Section 238.715 Roof and Side Structure Integrity

To demonstrate sufficient roof and side structure integrity, Tier III trainsets (and Tier I trainsets designed to alternative crashworthiness standards under appendix G) must comply with the requirements in § 238.215, ''Rollover strength,'' and § 238.217, ''Side structure.'' These Tier I requirements in §§ 238.215 and 238.217 are thereby broadly applicable to both new trainset classifications in this final rule. FRA did not receive any comments on this section and FRA is adopting it as proposed. Accordingly, as this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, see 81 FR 88006, 88029.

Section 238.717 Truck-to-Carbody Attachment

This section contains requirements to demonstrate the integrity of truck-to-carbody attachments on a Tier III trainset (or a Tier I trainset designed to

alternative crashworthiness standards under appendix G) during a dynamic impact. In commenting on the NPRM, Alstom recommended FRA clarify that the performance metric in paragraph (c) of this section is the ultimate strength of the truck materials. Paragraph (c) provides an alternative to demonstrating compliance with the quasi-static load requirements applied on the mass of the truck at its CG in paragraph (b)(3) of this section. Instead, paragraph (c) requires demonstrating the truck remains attached after a dynamic impact under the nominal conditions in the dynamic collision scenario described in § 238.705(a). Because paragraph (b)(3) limits demonstrating compliance to a truck and carbody meeting deceleration requirements specified in paragraphs (b)(3)(i) and (ii), respectively, paragraph (c) may alternatively be used to demonstrate truck-to-carbody attachment when the requirements in paragraph (b)(3) are exceeded. To comply with paragraph (c), it must be demonstrated that the truck undergoing evaluation has remained attached to the carbody after the trainset has been subjected to a dynamic collision scenario as described in § 238.705(a). FRA recognizes that the collision scenario in § 238.705(a) results in deformation of the carbody structure, and allowance for such deformation is consistent with an evaluation of the truck-to-carbody attachment that is based on ultimate strength, as FRA intended for paragraph (c). Accordingly, in response to Alstom's comment, FRA makes clear that the required performance metric in paragraph (c) is based on ultimate strength.

As a separate comment, Alstom requested that FRA make clear this section ''supersedes'' the requirements contained in § 229.141(a)(5) of this chapter, which applies to MU locomotives built new after April 1, 1956, that are operated in trains having a total empty weight of 600,000 pounds or more. Section 229.141(a)(5) of this chapter provides that the strength of the means of locking the truck to the body shall be at least the equivalent of an ultimate shear value of 250,000 pounds. However, FRA notes that the required truck attachment strength in § 238.717 is intended to be equivalent to an ultimate shear value of 250,000 pounds. Consequently, the requirements of § 238.717 are harmonious with the requirements of § 229.141(a)(5) of this chapter. Nonetheless, in response to Alstom's comment, FRA makes clear that the requirements of § 229.141(a)(5) of this chapter are inapplicable to Tier III and Tier I alternative trainsets subject to § 238.717.

FRA did not receive any other comments on this section and FRA is adopting it as proposed. As this portion of the final rule is identical to the proposed version, the analysis provided in the NPRM is not being repeated here, see 81 FR 88006, 88029–88030.

Glazing

Section 238.721 Glazing

This section contains the requirements for exterior glazing (*i.e.,* side- and end-facing exterior windows and windshields) to be installed on Tier III trainsets. APTA and TCRR both commented on this section as proposed in the NPRM. The comments focused on three discrete areas: Conduct of a comprehensive analysis, ballistic impact resistance requirements, and certification of the glazing material. Having considered the comments received, this section of the final rule reflects several changes from the NPRM, as explained below. Otherwise, FRA has adopted the requirements as proposed in the NPRM, and FRA is not repeating the analysis in the NPRM supporting and explaining those provisions remaining the same, see 81 FR 88006, 88030–88032.

Comprehensive Analysis

Both APTA and TCRR recommended deleting as unnecessary the requirement in proposed paragraph (a) of this section to conduct a comprehensive analysis identifying and addressing glazing safety issues associated with operating in a Tier III environment as part of the railroad's Safe Operation Plan for Tier III Passenger Equipment. APTA stated that specific requirements for Tier III glazing were adequately defined in the other paragraphs of this section, and were based on the operating environment for Tier I passenger equipment and the protected ROW required by FRA regulations under 49 CFR parts 213 and 236 for the dedicated high-speed portions. APTA also commented that compliance with the other paragraphs of this section will permit Tier III trainsets to be interoperable on the national rail network. Similarly, TCRR believed that compliance with the performance requirements contained in the other paragraphs proposed in this section should be the only regulatory requirements necessary to demonstrate suitability for Tier III trainset glazing and will assure interoperability throughout the national rail network. TCRR added that even if proposed paragraph (a) was intended to ensure that the ROW is adequately protected against potential hazards to the glazing there is no need to specify such a requirement here as other provisions of FRA's regulations adequately cover the topic, citing FRA's requirement for a ROW barrier plan, under 49 CFR 213.361, and the HSR–125 plan, under 49 CFR 236.1007.

In the final rule, FRA has not adopted the requirement proposed in paragraph (a) for railroads to conduct a comprehensive analysis of their systems to identify and address glazing safety issues their systems present for Tier III operations. Moreover, as explained further in the discussion under Discussion of Comments and Conclusions, section IV, neither this section nor any section in the final rule text refers to analyses required under a Tier III Safe Operation Plan. However, this section does require railroads to properly support and document glazing safety determinations, notably for the ballistic-resistance properties of the glazing material and for use of alternative requirements in a non-cab, side-facing window intended to be a breakable emergency window exit, for which specific FRA approval is required. FRA, based on input provided by the ETF, is working towards developing procedures and processes to provide such FRA approval, as discussed under Discussion of Comments and Conclusions, section IV, above. FRA will of course also work with any proposed Tier III operation to ensure that the requirements of this section are properly implemented.

Separately, because FRA has not adopted proposed paragraph (a), the paragraph ordering in this final rule begins with proposed paragraph (b), which is designated paragraph (a). Subsequent paragraphs proposed in the NPRM are designated accordingly in conformance, with the exception of the certification requirements in paragraph (e) in this final rule, discussed below.

Ballistic Penetration Resistance Requirements

In its comments on this section, APTA disagreed with FRA's proposal under paragraph (b)(5) of the NPRM that ballistic penetration resistance be sufficient to protect cab occupants from the risks and hazards identified by the railroad as part of its Tier III Safe Operation Plan, at a minimum meeting the protection requirements in appendix A to part 223 of this chapter. Instead, APTA suggested the regulation should require compliance with the ballistic impact protection requirement in appendix A to part 223, specifically in paragraphs (b)(10)(i) or (11)(i) of that

appendix, as appropriate. APTA stated that due to the interoperability requirements for Tier III equipment, the ballistic impact requirements must be standardized rather than vary for each railroad. APTA also stated that FRA has previously indicated the current 22 caliber bullet requirement in appendix A to part 223 has proven effective, and therefore APTA recommended retaining the current requirement for Tier III equipment. Further, in line with its comments on proposed paragraph (a), and noting that the existing requirement has shown through a long history to be adequate for conventional equipment, APTA suggested that no reference to a Tier III Safe Operation Plan is necessary. In addition, APTA expressed concern that changing the ballistic requirement has implications not just for Tier III equipment but for everything that is currently operating in North America and needs to be evaluated in another forum that involves all affected stakeholders.

In its comments, TCRR agreed with APTA and stated it did not see the merits of requiring each railroad to perform a risk assessment to form the basis for any performance requirements for glazing as suggested in proposed § 238.721(b)(5). Instead, TCRR recommended that the regulation include specific ballistic impact requirements that are applicable to glazing on all Tier III trainsets, to assure compatibility and interoperability of Tier III trainsets over the general railroad network. Additionally, TCRR stated that the current 22 caliber bullet requirement should apply to both end-facing and side-face exterior glazing in the cab, as well as in non-cab areas, to assure that both the passengers and crew in a Tier III trainset are afforded the same protection.

FRA notes that ballistic protection for cab glazing was discussed in detail during the RSAC glazing task group meetings, as stated in the NPRM. In particular, during those meetings, labor representatives asserted that ballistic protection from a larger diameter projectile, differing from the size required for Type I glazing by part 223, would enhance the overall safety of the cab occupants. Much discussion was focused on this point, but a review of the available information on the impact characteristics of reasonable ballistic scenarios (projectile size and terminal velocity), and a review of the statistics related to glazing failure due to ballistic impact, proved inconclusive. This is one area where the task group could not agree on a consensus approach. Therefore, the decision on ballistic requirements for cab glazing was referred to FRA.

At this time, FRA does not have sufficient evidence to suggest a particular risk or hazard exists facing all potential Tier III systems to warrant a change from current ballistic requirements in part 223. However, even without such a risk or hazard facing all Tier III systems in common, the circumstances of a specific Tier III operation may warrant additional consideration and protection for that operation. To be consistent with the approach to Tier III safety in this rule, railroad safety elements subject to elements present within a specific Tier III operation need to be addressed in a manner appropriate to that operation, reflecting the level of service, operating environment, operational conditions, etc. Accordingly, while the ballistic penetration resistance requirement in paragraphs (b)(10)(i) and (11)(i) of appendix A to part 223 remains the minimum requirement in this final rule—namely, protection from a 22 caliber long rifle lead bullet of 40 grains in weight impacting at a minimum velocity of 960 feet per second, this final rule allows for the use of a ballistic penetration resistance standard that provides greater protection. Nor would use of a more stringent standard necessarily affect equipment interoperability any more than in any situation where a particular operation uses a standard more stringent than the minimum standard specified in the regulation. Consequently, even though FRA has not adopted the reference to a Tier III Safe Operation Plan in proposed paragraph (b)(5), a Tier III operation is in no way restricted from protecting against only a 22 caliber long-rifle bullet if circumstances known to the railroad warrant additional protection—whether for end-facing glazing in paragraph (a)(5) of this final rule or for side-face glazing in paragraph (b)(2) of this final rule (proposed paragraph (c)(2)).

FRA has continued to examine the appropriateness of the ballistic impact requirement with the ETF, but no consensus within the ETF was reached on this topic. FRA has also engaged in additional research. At the behest of ETF industry members, FRA has subjected representative samples of forward- and side-facing glazing to 22 caliber long rifle and 9 mm ballistic impact tests. The use of a 9 mm bullet for ballistic impact testing reflects the alternative ballistic penetration resistance requirement in 49 CFR 238.421(c)(3)(i) for Tier II equipment ordered prior to May 12, 1999, which FRA believes provides an equivalent level of ballistic protection. However, the results of the testing were not sufficient to confirm whether use of the different caliber bullets results in a different level of test severity or whether the tests are indeed equivalent.

Glazing Certification

Commenters APTA and TCRR also raised concern over the NPRM's approach to the certification of glazing material in proposed § 238.721(b)(6). As a threshold matter, APTA requested that the rule make clear the glazing manufacturer is responsible for certification of each type of glazing material supplied. APTA then stated that the rule, in turn, require testing to be done either by an independent laboratory or the manufacturer with allowance for FRA to witness the testing. Similarly, TCRR believed that the proposal would create unnecessary confusion regarding glazing certification and instead recommended FRA continue with the current approach to glazing certification in part 223. TCRR stated that the current requirements under appendix A to part 223 have worked very well and provide the railroads and carbuilders assurance that all glazing materials they receive are produced from a lot that has been properly tested. TCRR cautioned that before taking a new approach to glazing certification, discussions are needed involving the glazing manufacturers and possible testing agencies to better understand both how any proposed changes would be addressed and the practical realities and consequences of the proposed changes.

FRA recognizes that the proposed regulatory language created confusion regarding who is ultimately responsible for certifying that the glazing material is compliant with FRA's requirements. As such, the final rule text makes clear that the glazing manufacturer is ultimately responsible for this certification. In the NPRM, FRA had intended to convey that the glazing manufacturer can certify the glazing material based on tests performed by an independent third party (*e.g.,* a laboratory, facility, or underwriter), or tests performed by the glazing manufacturer itself. FRA did not intend to imply that another party was ultimately responsible for certifying the glazing materials. Further, for clarity, the glazing certification requirements are contained in their own paragraph (paragraph (e)) in this section of the final rule, rather than combined with other glazing requirements. These glazing certification requirements apply to all glazing material used on Tier III trainsets.

Demonstrating Alternative Safety for Breakable, Emergency Window Exits

Finally, consistent with APTA's comments concerning the NPRM's proposal for a Tier III Safe Operation Plan, APTA commented that proposed paragraph (d)(2)'s alternative requirements for non-cab, side-facing exterior window glazing should not reference a Tier III Safe Operation Plan. APTA stated that during the design review process information would be available that is necessary to demonstrate an equivalent level of glazing safety for a side-facing exterior window intended to be breakable and serve as an emergency window exit, and that its proposal for a new § 238.110 would specifically reference this design review requirement to be included in the pre-revenue qualification plan.

As discussed above, this § 238.721 does require railroads to properly support and document glazing safety determinations. Specifically, paragraph (c)(2) of this section requires such support and documentation for use of alternative glazing requirements in a non-cab, side-facing exterior window intended to be a breakable emergency window exit. FRA approval is also required. Nonetheless, as noted above and discussed under proposed subpart J in the Discussion of Comments and Conclusions, section IV, FRA, based on input provided by the ETF, is working towards developing procedures and processes to provide such FRA approval. As always, FRA will work with any proposed Tier III operation to ensure that the requirements of this section are properly implemented.

Brake System

Section 238.731 Brake System

This section introduces brake system requirements for Tier III passenger trainsets. As articulated in the NPRM, development of these requirements was identified as one of the goals for this first Tier III rulemaking to facilitate planned equipment acquisitions. These requirements represent a balance between maintaining compatibility with existing Tier I equipment and the adoption of service-proven techniques to protect against potential risks encountered with high-speed operations. A concerted effort was made to develop technology-neutral requirements, and the NPRM identified various requirements to be determined by a railroad and included in the railroad's Tier III Safe Operation Plan or ITM Plan.

In response to the comments received, FRA is making changes to this section from the NPRM's proposal, as explained below. Additionally, FRA is making a minor editorial change to reference an ITM ''program'' rather than ITM ''plan.'' Otherwise, FRA has adopted the requirements as proposed in the NPRM, and FRA is not repeating the analysis in the NPRM supporting and explaining those provisions remaining the same, see 81 FR 88006, 88032–88034.

In its comment on this section, APTA recommended that the determinations identified in the NPRM to be included in a Tier III Safe Operation Plan be left to the railroad to address at various stages of equipment design reviews. APTA offered in support of this position that certain determinations to be included in a Tier III Safe Operation Plan are already required under other FRA regulations. As discussed earlier, the requirements of this final rule do not reference a Tier III Safe Operation Plan, and this section contains no such references as proposed in the NPRM. However, this section does provide for FRA approval of various determinations made by the railroad, consistent with FRA's closer oversight of high-speed train operations.

Accordingly, paragraph (b) requires the railroad to define the worst-case adhesion conditions under which each Tier III trainset's brake system must stop the passenger trainset from its maximum operating speed within the prevailing signal spacing, as approved by FRA. The paragraph is intended to ensure that the railroad formally establish the worst case-adhesion conditions for use in procuring individual trainsets. Similarly, paragraph (c)(2) requires the railroad to specify the locations onboard its Tier III trainsets where a crewmember can initiate an irretrievable emergency brake application, as approved by FRA.

FRA approval of railroad determinations is required in several provisions under paragraph (d). Paragraph (d)(1) requires the railroad to identify the locations onboard its Tier III trainsets where a mechanism to initiate the passenger brake alarm is installed. Paragraph (d)(4) requires the railroad to define the timeframe in which engineers must acknowledge a passenger brake alarm after the trainsets have safely cleared the boarding platform, for the engineer to retain full control of the trainset, and to define the method used to confirm that the trainsets did in fact safely clear the boarding platform. In addition, paragraph (d)(6) requires the railroad to specify the procedures for engineers to retrieve full service brake application if the timeframe to acknowledge a passenger brake alarm has passed and a brake application has been automatically initiated.

FRA approval of railroad determinations is also required under paragraph (e), which addresses how trainsets without fully functional electric braking are to be safely operated, particularly to ensure thermal-related brake system damage does not occur. Paragraph (e)(1) requires that the railroad specify the allowable stopping distance not to be exceeded in the event of a power loss or failure of the dynamic or regenerative brake. FRA expects the railroad to provide a means for automatically reducing the maximum allowable train speed, based on feedback from the on-board monitoring and diagnostic system specified in § 238.731(n), so the trainset can safely stop using friction braking alone within the allowable stopping distance. Additionally, paragraph (e)(2) requires the railroad to define the operating conditions under which the available friction braking effort alone can safely stop the trainset. For discussion of paragraph (e)(4), please see below.

FRA approval of railroad determinations is required under paragraph (f)'s main reservoir system requirements. Paragraph (f)(1) requires that main reservoirs be designed and tested using a recognized industry standard specified by the railroad and approved by FRA. This paragraph also provides that the railroad shall define the working pressure and rated temperature for main reservoirs in accordance with the designated standard, if different from the pressure and temperature otherwise specified in this paragraph. Further, paragraph (f)(2) requires the railroad to identify a recognized industry standard governing the drilling of steel main reservoirs.

FRA approval is required under paragraph (j)'s brake application/release requirements. Specifically, paragraph (j)(2) requires that the railroad establish the minimum brake cylinder pressure necessary to adjust from minimum service to full service brake application for proper train operation.

FRA approval is required under paragraph (m)'s slide protection and alarm requirements. Paragraph (m)(3) requires the railroad to specify the operational restrictions that apply when the wheel slide protection system fails to function as intended within pre-established, allowable parameters.

As noted above, the railroad determinations specified under paragraphs (b), (c)(2), (d)(1), (d)(4), (d)(6), (e)(1)–(2), (f)(1)–(2), (j)(2), and (m)(3) do not reference a Tier III Safe Operation Plan but do require FRA approval. However, as discussed under Discussion of Comments and Conclusions, section IV, above, FRA

approval oversight was a major tenet of the proposed Tier III Safe Operation Plan requirement, and those requirements identified for inclusion in the Tier III Safe Operation Plan were selected to allow FRA to have some specific approval oversight of the railroad's determinations. Accordingly, those plan elements the NPRM identified in this section as needing specific FRA approval do require FRA approval in this final rule. Nonetheless, FRA will work with any proposed Tier III operation to ensure that the requirements of this section are properly implemented.

FRA notes that proposed paragraph (l), Leakage, did refer to the Tier III Safe Operation Plan. Paragraph (l) of the final rule contains no such reference. Specifically, the Air Consumption Analysis required under this paragraph shall be developed as part of the railroad's ITM program.

Based on APTA's comments, FRA is taking a somewhat different approach regarding the proposed reference in paragraph (n) to a Tier III Safe Operation Plan. Paragraph (n) requires each Tier III trainset to be equipped with a brake system health monitoring and diagnostic system to automatically assesses the functionality of the brake system for the entire trainset, both before the trainset departs and while it is en route. As proposed, the railroad must document the details of the monitoring system and diagnostic system, and the means for communicating trainset brake system functionality to the engineer. In its comment, APTA recommended that rather than include this information in a Tier III Safe Operation Plan, a railroad should include this information in its ITM program. FRA agrees with and is adopting APTA's recommendation. It accomplishes the goals of this paragraph, and trainset monitoring and diagnostics relate to inspection, testing, and maintenance. It will also provide FRA approval oversight through the ITM program approval process.

In other comments on this section, APTA recommended that FRA include in paragraph (e)(4) a requirement that railroads conduct additional analysis and testing to determine the maximum safe operating speed for various percentages of operative friction brakes.

As proposed, paragraph (e)(4) requires railroads to determine through analysis and testing the maximum speed for safely operating and stopping their Tier III trainsets using the friction brake system alone without causing thermal-related damage to the equipment or infrastructure. APTA recommended the additional analysis and testing to adequately quantify the braking performance for movement of defective equipment. TCRR's comments on the NPRM were in agreement with APTA's on this paragraph. TCRR cautioned that the movement of defective equipment requirements must refer to paragraph (e) of this section and require railroads to conduct appropriate analysis and testing to determine the maximum safe operating speed for various percentages of operative friction brakes. FRA agrees with APTA's and TCRR's comments.

Accordingly, FRA is adopting the recommendation in paragraph (e) to make clear further testing and analysis is required to determine the safe maximum operating speed for various percentages of friction brakes less than 100-percent operative. FRA expects the railroad to include these determination in its ITM program.

FRA also received comments on paragraph (o) of this section from APTA and Alstom. As proposed, this paragraph requires Tier III equipment to be equipped with a means to secure unattended equipment against unintentional movement. Because the securement technique may be technology-specific to a particular trainset, FRA proposed that the procedures and means necessary for securing unattended equipment based on the grade conditions be included in the Tier III Safe Operation Plan, which in turn could be used to help demonstrate the effectiveness of the securement method(s). FRA further proposed to define the term ''unattended equipment'' to have the same meaning as in § 238.231(h)(4), which provides that unattended equipment is equipment left standing and unmanned in such a manner that a qualified person cannot readily control the brake system of the equipment. FRA intended the cross reference to § 238.231(h)(4) to be limited specifically to the definition of ''unattended equipment,'' for consistency and to remove any ambiguity as to the meaning of the term, because FRA has already defined the term in this part 238.

In APTA's comment on paragraph (o), APTA objected to the cross reference to § 238.231(h)(4). APTA raised concern that its inclusion in the regulatory text could sweep in the Tier I requirement that Tier III trainsets be equipped with a parking or handbrake. APTA stated that was not part of the consensus agreement on the proposed rule text presented to FRA in which wheel chocks could be used to secure unattended equipment under certain circumstances. Nonetheless, APTA did agree to FRA's use of the modifier ''unattended'' in this paragraph to describe the type of equipment to be secured, noting that technical specifications normally state that the equipment can be left for an indefinite time period, which corresponds to unattended. Further, consistent with its other comments, APTA stated that this paragraph's reference to a Tier III Safe Operation Plan was unnecessary because the physical means for securing the trainset will be addressed during the design review and the procedures for securing the trainset will be defined in the railroad's operating rules. In its comments on this paragraph, Alstom similarly objected to the addition of the cross reference to § 238.231(h)(4), stating it was not consistent with the consensus agreement on the proposed regulatory text to permit the use of wheel chocks to secure unattended equipment under certain conditions.

FRA makes clear that the reference to § 238.231(h)(4) was not intended to mean that § 238.231(h)(4)'s requirements for parking or hand brakes apply to this § 238.731(o). As explained above, the reference was intended to capture only the definition of ''unattended'' and not sweep into this paragraph requirements concerning parking or hand brakes. However, to guard against ambiguity and for consistent application of the term, in this paragraph of the final rule FRA has incorporated § 238.231(h)(4)'s definition of ''unattended.'' Further, FRA agrees with APTA's recommendation not to include the reference to the Tier III Safe Operation Plan, and it is not included in this paragraph. Yet, FRA believes it necessary to approve the procedures and means necessary for securing unattended equipment on the grade conditions identified, and this paragraph requires such approval. Inclusion in the railroad's operating rules alone is not sufficient as FRA does not approve railroad operating rules under part 217 of this chapter. Further, issues surrounding how equipment will be properly secured while unattended are operational in nature and thus capturing those issues in a design review is not sufficient. In the interim, FRA will of course work with any proposed Tier III operation to ensure that the specific procedures and means of securing unattended equipment as required under this paragraph are properly addressed and documented. In this regard, and as FRA made clear in the NPRM, certain brake system requirements are imposed by Federal statute, 49 U.S.C. ch. 203. Specifically, 49 U.S.C. 20302(a)(1)(B) requires ''efficient handbrakes.'' Railroads must

ensure that those statutory requirements are addressed.

Interior Fittings and Surfaces

Section 238.733 Interior Fixture Attachment

This section contains requirements for interior fixture attachment strength for Tier III trainsets. This section relates to strength requirements for seats and luggage racks in §§ 238.735 and 238.737, respectively, to help prevent and mitigate hazards associated with occupants impacting interior objects and surfaces during a collision.

In its comments on this section and §§ 238.735 and 238.737, APTA recommended that FRA not reference the attachment strength requirements in § 238.233, Interior fittings and surface, for Tier I equipment. The NPRM proposed to allow compliance with those strength requirements, specifically, 8g longitudinal, 4g vertical, and 4g lateral, as an option instead of using Railway Group Standard GM/RT2100 and 5g longitudinal, 3g vertical, and 3g lateral attachment strength requirements. As discussed in the ETF's May 2017 meeting, APTA believes the 5g, 3g, and 3g attachment strength requirements are sufficient to serve as the minimum safety requirements and are consistent with the dynamic collision requirements in § 238.705(b)(2), which provides that, if GM/RT2100 is used, the average deceleration experienced by each vehicle in a Tier III trainset may not exceed 5g during any 100-ms period. APTA added that, in developing the NPRM, the ETF consensus for use of the strength requirements in § 238.233 was for Tier I alternative trainsets, as reflected in proposed paragraphs (i) though (k) of appendix G to this part. According to APTA, the ETF's consensus was for Tier III trainsets to comply with the relevant strength requirements in Railway Group Standard GM/RT2100, Issue Four, with the additional requirement to apply a 3g vertical load rather than a 1g vertical load. As noted above, APTA contends that the 5g, 3g, and 3g attachment strength requirements are more harmonious with the Tier III requirements because they are tied to a maximum crash pulse requirement, unlike the 8g, 4g, and 4g requirements in § 238.223.

FRA is not adopting APTA's recommendation. FRA always intended to provide the two options for compliance, as discussed in the NPRM. The first option, in paragraph (a)(1) of this section, allows compliance with the requirements of § 238.233 and APTA PR–CS–S–006–98, Rev. 1, ''Standard for Attachment Strength of Interior Fittings for Passenger Railroad Equipment,'' Authorized September 2005. The second option, in paragraph (a)(2) of this section, allows compliance with section 6.1.4, ''Security of furniture, equipment and features,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, provided: The test conditions of § 238.705(b)(2) are met; interior fixture attachment strength is based on a minimum of 5g longitudinal, 3g vertical, and 3g lateral acceleration resistance; and use of the GM/RT standard is carried out in accordance with any conditions identified by the railroad, as approved by FRA. (This last condition has been modified from the NPRM consistent with FRA's discussion regarding proposed subpart J, under Discussion of Comments and Conclusions, section IV, above.)

The acceleration-based performance standards in § 238.233 and APTA standard PR–CS–S–006–98, Rev. 1, were established after years of industry practice designing interior fittings to withstand the forces due to accelerations of 6g longitudinally, 3g vertically, and 3g laterally, which FRA specifically found to be inadequate to protect against occupant injury (see 64 FR 25540, 25614).[16] The accident performance of interior fixtures designed to comply with § 238.233 and the APTA standard support their continued use for interior attachment strength. However, FRA continues to recognize that some Tier III passenger equipment may not experience accelerations of 8g longitudinally, 4g vertically, or 4g laterally during the dynamic collision scenario in § 238.705, or at higher-speed collisions resulting in collapse of the occupied volume. FRA acknowledges that equipment that does not experience large decelerations during collisions does not need to be designed to these standards in § 238.233 and APTA standard PR–CS–S–006–98, Rev. 1. Accordingly, FRA developed an alternative attachment strength option consistent with international design standards, in paragraph (a)(2) of this section. FRA views the alternative as providing an equivalent level of safety to the now longstanding acceleration resistance requirements in § 238.233 and the APTA standard, with the qualification that no acceleration-based load higher than 5g is experienced as provided in paragraph (a)(2) of this section. FRA finds no additional burden is imposed by providing two options to demonstrate compliance with this section, and therefore declines to adopt APTA's suggestion to remove the first option.

As noted above, paragraph (a)(2)(iii) provides for use of the GM/RT standard in accordance with any conditions identified by the railroad and approved by FRA. According to APTA, in its comments on this NPRM, the proposed reference to a Tier III Safe Operation plan in this paragraph was unnecessary because the criteria for the acceleration pulse in the Tier III collision scenario must be met as provided in § 238.705(b)(2). Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the conditions involving the option to comply with paragraph (a)(2) rather than paragraph (a)(1) is necessary. FRA seeks to ensure that compliance with paragraph (a)(2) provides an equivalent level of safety to the existing requirements in § 238.233 and the APTA standard, and that no acceleration-based load higher than 5g is experienced. Nonetheless, as noted above and discussed under proposed subpart J in the Discussion of Comments and Conclusions, section IV, FRA, based on input provided by the ETF, is working towards developing procedures and processes to provide such FRA approval. As always, FRA will work with any proposed Tier III operation to ensure that the requirements of this section are properly implemented. Because FRA has otherwise adopted the substantive requirements of this section as proposed in the NPRM, FRA is not repeating the full analysis in the NPRM supporting and explaining the requirements of this section, see 81 FR 88006, 88034–88036.

FRA does note it is incorporating by reference APTA PR–CS–S–006–98, Rev. 1 (previously designated as SS–C&S–006), ''Standard for Attachment Strength of Interior Fittings for Passenger Railroad Equipment,'' Authorized September 2005, in paragraph (a)(1) of this section and in paragraph (i) of appendix G to this part; and section 6.1.4, ''Security of furniture, equipment and features,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards

[16] When developing the requirements of the 1999 final rule, FRA concluded that due to the injuries caused by broken seats and other loose fixtures, which were designed to withstand the forces due to accelerations of 6g in the longitudinal direction, 3g in the vertical direction, and 3g in the lateral direction, as revealed in FRA and NTSB investigations of passenger train accidents, the design practice was inadequate.

Board Ltd., December 2010 in paragraph (a)(2) of this section and § 238.741(b)(2).

APTA PR–CS–S–006–98 addresses fittings used in commuter and intercity railcar and locomotive cab interiors. It specifies the minimum strength and attachment strength for interior sub-systems, including overhead luggage racks, stanchions and handholds, windscreen and partitions, food service equipment, and miscellaneous interior fittings. This standard also contains recommendations for design requirements and design practices for such interior sub-systems. APTA PR–CS–S–006–98 is available to all interested parties online at *www.apta.com*. Additionally, FRA will maintain a copy available for review.

Section 6.1.4 of GM/RT2100 contains requirements for securement of furniture, on-board equipment, and other trainset features to help mitigate against injuries to passengers and crew from secondary impacts within the occupied volume. GM/RT2100 is available to all interested parties online at *www.rgsonline.co.uk/Railway_Group_Standards*. Additionally, FRA will maintain a copy available for review.

Section 238.735 Seat Crashworthiness (Passenger and Cab Crew)

This section contains the seat strength requirements for Tier III trainsets and relates to the strength requirements for interior fixtures and luggage racks in §§ 238.733 and 238.737, respectively, as noted above. APTA and Alstom both commented on this section. Specifically, APTA commented on the proposed passenger seating requirements in paragraph (a) based on the same premise as its comment on § 238.733(a), as discussed above. APTA recommended that the option in proposed paragraph (a)(1) to comply with § 238.233 and APTA standard PR–CS–S–006–98 not be included. Instead, APTA suggested that the sole option to demonstrate compliance would be based on section 6.2, ''Seats for passengers, personnel, or train crew,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, under the same acceleration resistance conditions APTA recommended for § 238.733(a)(2)(ii). As the underlying issue APTA raises applies equally for both sections, FRA is not repeating the full discussion here. For the reasons discussed under § 238.733(a), above, FRA is not adopting APTA's recommendation and is therefore retaining both compliance options under paragraph (a).

Similarly, APTA also commented that the proposed reference to a Tier III Safe Operation Plan under paragraph (a)(2)(iii) was unnecessary because the criteria for the acceleration pulse in the Tier III collision scenario must be met as provided in § 238.705(b)(2). Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the conditions involving the option to comply with paragraph (a)(2) rather than paragraph (a)(1) is necessary for safety. Accordingly, paragraph (a)(2)(iii) provides for such FRA approval rather than refer to a Tier III Safe Operation Plan. Please see § 238.733(a)(2)(iii), above, and proposed subpart J, under Discussion of Comments and Conclusions, section IV, above, for a fuller discussion of the comment and this requirement. FRA notes that Alstom, in commenting on this section in the NPRM, stated that paragraphs (a)(1) and (2) are not fully equivalent in terms of scope of application. Although the requirements of the paragraph are different, FRA has always intended these requirements to provide an equivalent level of safety, given the different circumstances surrounding their application. FRA will work with any proposed Tier III operation to ensure that the requirements of paragraph (a) are properly implemented.

FRA notes it is incorporating by reference APTA PR–CS–S–016–99, Rev. 2, ''Standard for Passenger Seats in Passenger Rail Cars,'' Authorized October 2010, in paragraph (a)(1) of this section and in paragraph (j) of appendix G to this part; and section 6.2, ''Seats for passengers, personnel, or train crew,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, in paragraph (a)(2) of this section.

APTA PR–CS–S–016–99 addresses row-to-row passenger seating in commuter and intercity railcars. APTA PR–CS–S–016–99 is available to all interested parties online at *www.apta.com*. Additionally, FRA will maintain a copy available for review. However, FRA makes clear the rule does not require compliance with section 6.0, ''Seat durability testing,'' of this APTA standard. Seat durability testing is beyond the scope of this regulation because the testing focuses on the optimal life of the seats—not their safety performance.

Section 6.2 of GM/RT2100 contains design specifications and tolerances for passenger and crew seating. GM/RT2100 is available to all interested parties online at *www.rgsonline.co.uk/Railway_Group_Standards*. Additionally, FRA will maintain a copy available for review.

Paragraph (b) contains requirements for the crashworthiness of seats provided for an employee in the cab of a Tier III trainset. Unlike passenger seating, FRA proposed in paragraph (b)(1) that cab seats must comply with the requirements in § 238.233(e), (f), and (g), and the performance, design, and test criteria of AAR–RP–5104, ''Locomotive Cab Seats,'' April 2008, which FRA proposed to incorporate by reference in paragraph (b)(2) and paragraph (k)(2) of appendix G to this part. Although not submitted as a comment, AAR made FRA aware that it is archiving AAR–RP–5104. FRA therefore requested assistance from the ETF during the May 2017 meeting, and a small work group was convened to address the problem. The group recommended back to the ETF to excerpt language from section 3 of AAR–RP–5104 that prescribes minimum loading requirements for the seat itself, and place that language into the final rule. When the recommendation was presented to the ETF, industry members were adamantly opposed, stating that the requirements in section 3 of AAR–RP–5104 were durability standards and not safety-related. In fact, APTA, in a comment submitted after the close of the comment period, recommended deleting the reference to AAR–RP–5104 and its proposed paragraph (b)(2) entirely, stating that proposed paragraph (b)(1) adequately defines the requirements for Tier III cab seating.

Resultantly, FRA has not adopted proposed paragraph (b)(2) and FRA is not including a requirement to comply with any portion of AAR–RP–5104. In turn, proposed paragraph (b)(1) is designated as (b) of this section. As proposed, paragraph (b) requires compliance with § 238.233(e), (f), and (g). However, with respect to the acceleration-based loading requirements specified in § 238.233(f), FRA makes clear in paragraph (b) that it expects for Tier III (and Tier I alternative) trainsets the cab seat to remain attached to the trainset structure when subjected to an 8g longitudinal acceleration-based load applied to the combined mass of the seat and a 95th-percentile male. FRA recognizes that this constitutes the more severe scenario to be tested. It is more severe than an 8g acceleration-based load applied solely to the mass of the cab seat. It is also more severe than testing under AAR–RP–5104, which provides for testing the seat with 250 pounds impacting the seatback at 3g. FRA concludes that if the cab seat can remain attached when subjected to an 8g acceleration-based load applied to the combined mass of the cab seat and

a 95th-percentile male, then the seat should remain attached under foreseeable collision scenarios.

Section 238.737 Luggage Racks

This section contains requirements to constrain the longitudinal and lateral motion of articles stowed in luggage racks, and relates to the strength requirements for interior fixtures and seats in §§ 238.733 and 238.735, respectively, as noted above.

FRA received no comments on paragraph (a) and has adopted it as proposed. Please see the discussion of paragraph (a) in the NPRM (81 FR 88006, 88036). Nonetheless, APTA commented on the proposed luggage rack strength requirements in paragraph (b) based on the same premise as its comments on §§ 238.733(a) and 238.735(a), as discussed above. APTA recommended that the option in proposed paragraph (b)(1) to comply with § 238.233 not be included. Instead, APTA suggested that the sole option to demonstrate compliance would be based on section 6.8, ''Luggage stowage,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, specifically under the same acceleration resistance conditions APTA recommended for §§ 238.733(a)(2)(ii) and 238.735(a)(2)(ii). As the underlying issue APTA raises applies equally here, FRA is not repeating the full discussion. For the reasons discussed under §§ 238.733(a) and 238.735(a), above, FRA is not adopting APTA's recommendation and is therefore retaining both compliance options under paragraph (b).

Similarly, APTA also commented that the proposed reference to a Tier III Safe Operation plan under paragraph (b)(2)(iii) was unnecessary because the criteria for the acceleration pulse in the Tier III collision scenario must be met as provided in § 238.705(b)(2). Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the conditions involving the option to comply with paragraph (b)(2) is necessary for safety. Accordingly, paragraph (b)(2)(iii) provides for such FRA approval rather than refer to a Tier III Safe Operation Plan. Please see §§ 238.733(a)(2)(iii) and 238.735(a)(2)(iii), above, and proposed subpart J, under Discussion of Comments and Conclusions, section IV, above, for a fuller discussion of the comment and this requirement. Further, FRA expects that in demonstrating compliance with this requirement, the railroad must address how the mass of the luggage was considered when applied to the loading conditions defined in paragraph (b)(2)(ii).

FRA notes it is incorporating by reference section 6.8, ''Luggage stowage,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, in paragraph (b)(2) of this section. Section 6.8 contains requirements for luggage stowage, either on the floor or in overhead racks. As noted above, GM/RT2100 is available to all interested parties online at *www.rgsonline.co.uk/Railway_Group_Standards*. Additionally, FRA will maintain a copy available for review.

Emergency Systems

Section 238.741 Emergency Window Egress and Rescue Access

This section establishes requirements for emergency egress and rescue access through windows or alternative openings in passenger cars as part of an emergency window egress and rescue access plan for Tier III trainsets. The ETF recognized that any regulation would need to allow multiple approaches to facilitate the adoption of service-proven, high-speed trainset technology. Specifically, the methods used to manufacture high-speed trainsets are often governed by consideration of the effects of aerodynamics and noise; together with the potential need to pressurize occupied compartments, these can affect the way window glazing is installed and mounted in some trainset designs. Therefore, the ETF recommended performance-oriented requirements to allow necessary flexibility where an appropriate safety case can be made.

FRA did not receive any comments on the requirements of this section as described in the NPRM. However, FRA is clarifying in paragraph (b) the reference to a Tier III ITM program, rather than to a Tier III ITM plan, as proposed in the NPRM. Otherwise, FRA is adopting this section as proposed. Accordingly, as this section of the final rule is virtually identical to the proposed version, the full analysis and discussion of this section provided in the NPRM is not repeated here (see 81 FR 88006, 88019–88020).

Section 238.743 Emergency Lighting

This section contains the emergency lighting requirements for Tier III trainsets. As proposed, paragraph (a) provides that the requirements are the same as the emergency lighting requirements in § 238.115, except for those specific to emergency lighting back-up power systems in paragraph (b). Paragraph (b), in turn, permits compliance with alternative, crash loading resistance requirements, to demonstrate the capability of back-up power systems to function after the initial shock caused by a collision or derailment.

APTA commented on the proposed back-up power requirements in paragraph (b) based on the same premise as its comments on §§ 238.733, 238. 735, and 238.737, above. APTA recommended that the option in proposed paragraph (b)(1) of this section to comply with the acceleration resistance requirements in § 238.115 not be included. Instead, APTA suggested that the sole option to demonstrate compliance be based on section 6.1.4, ''Security of furniture, equipment and features,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, under the same conditions APTA recommended for §§ 238.733(a)(2)(ii), 238.735(a)(2)(ii), and 238.737(b)(2)(ii). As the underlying issue APTA raises generally applies equally for all sections, FRA is not repeating the full discussion here, and generally for the reasons discussed under these sections, above, FRA is not adopting APTA's recommendation. This paragraph retains both compliance options. Further, FRA makes clear that § 238.115 is contained in subpart B of part 238, and the scope of subpart B applies to all passenger equipment, regardless of operating speed. Consequently, FRA could have included specific back-up power requirements for Tier III trainsets in subpart B's § 238.115 but chose instead to place them here in subpart H for ease of reference.

FRA notes § 238.743(b)(1) in the final rule references the acceleration-based loads in § 238.115(a)(4)(ii), which are 8g, longitudinally, and 4g, laterally and vertically. In the NPRM, FRA inadvertently referenced § 238.115(b)(4)(ii), which was clear error because there is no such paragraph in § 238.115. FRA has corrected the reference.

Paragraph (b)(2) provides the second option for demonstrating the crashworthiness of emergency lighting back-up power systems. A railroad may use the loading requirements defined in section 6.1.4, ''Security of furniture, equipment and features,'' of GM/RT2100, under specified conditions. In the NPRM, FRA proposed that back-up power systems have an attachment strength sufficient to resist minimum loads of 5g longitudinally, 3g laterally, and 3g vertically. However, FRA's

proposal was inadvertently overbroad. FRA intended for the back-up power supply to remain functional after being subjected to the initial shock of a collision or derailment, whether or not remaining attached in place.

Consistent with its comments on similar proposed provisions, APTA also commented that the proposed reference to a Tier III Safe Operation plan under paragraph (b)(2)(iii) was unnecessary because the criteria for the acceleration pulse in the Tier III collision scenario must be met as provided in § 238.705(b)(2). Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the conditions involving the option to comply with paragraph (b)(2) is necessary for safety. Accordingly, paragraph (b)(2)(iii) provides for such FRA approval rather than refer to a Tier III Safe Operation Plan. Please see §§ 238.733(a)(2)(iii), 238.735(a)(2)(iii), and 238.737(b)(2)(iii), above, and proposed subpart J, under Discussion of Comments and Conclusions, section IV, above, for a fuller discussion of the comment and this requirement.

FRA notes it is incorporating by reference section 6.1.4, ''Security of furniture, equipment and features,'' of Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, into paragraph (b)(2) of this section. Section 6.1.4 contains requirements for the securement of furniture, equipment, and other features. As noted above, GM/RT2100 is available to all interested parties online at *www.rgsonline.co.uk/Railway_Group_Standards*. Additionally, FRA will maintain a copy available for review.

Cab Equipment

Section 238.751 Alerters

This section contains requirements for alerters on Tier III passenger trainsets. In commenting on this section in the NPRM, APTA recommended removal of the proposed references to a Tier III Safe Operation Plan, consistent with its comments on proposed subpart J. As discussed below, this section does not include references to a Tier III Safe Operation Plan but does ensure FRA oversight. Otherwise, FRA has adopted this section as proposed and has therefore not repeated the full analysis of this section in the NPRM (see 81 FR 88006, 88037–88038).

As proposed in the NPRM, paragraph (b) would have required the railroad to determine the appropriate time period within which the engineer must acknowledge the alerter and include that determination in the railroad's Tier III Safe Operation Plan for review and approval by FRA. In its comment, APTA stated that inclusion in the Safe Operation Plan was unnecessary because the basis for setting the alerter control timing would be addressed during the design review process and FRA could review the railroad's alerter timing determination then. Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the periodicity of the alerter alarm, as well as the time period within which the engineer must react to that alarm, is necessary for safety. Nonetheless, as noted above and discussed under proposed subpart J in the Discussion of Comments and Conclusions, section IV, FRA, based on input provided by the ETF, is working towards developing procedures and processes to provide such FRA approval. As always, FRA will work with any proposed Tier III operation to ensure that the requirements of this paragraph and this section are properly implemented. In this regard, FRA makes clear it intends alerter control timing to be set by the railroad taking into consideration maximum train speed and capabilities of the signal system.

As proposed in the NPRM, paragraph (d) would have required specifying in the railroad's Tier III Safe Operation Plan the necessary actions of the engineer responding to a full-service brake application initiated after the engineer failed to properly acknowledge the alerter. APTA, in its comment, stated that this was also unnecessary as these required actions would be contained in the railroad's operating rules and the ''engineer's training program.'' Again, although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval is necessary, namely, of the actions specified for the engineer to recover the full-service brake application. Inclusion in the railroad's operating rules is not sufficient as FRA does not approve railroad operating rules under part 217 of this chapter. Additionally, these procedures are not intended to be specified in the locomotive engineer certification program required under part 240 of this chapter. Thus, simple inclusion in a training program does not provide the necessary review and approval mechanism FRA desires. Nonetheless, as FRA, based on input provided by the ETF, is working towards developing specific procedures and processes for obtaining such approval, FRA will work with any proposed Tier III operation to ensure the requirements of this paragraph are properly implemented.

Finally, as proposed in the NPRM, paragraph (e) would have required a railroad electing to use alternate technology to an alerter, to provide the function(s) of an alerter, to conduct a hazard analysis as part of its Tier III Safe Operation Plan. The intent behind the analysis was to demonstrate that the alternate alerter technology provided an equivalent level of safety. APTA, in its comment, stated that inclusion in a Tier III Safe Operation Plan was unnecessary because the demonstration of an equivalent level of safety would be performed during the design review process, with the results of the safety analysis being used to support the determination. Although FRA agrees not to include a reference to a Tier III Safe Operation Plan, FRA continues to believe that FRA approval of the equivalency determination is necessary for safety, and FRA will work with any proposed Tier III operation to ensure that the requirements of this paragraph are properly implemented, as discussed above. In this regard, FRA has clarified that the required analysis is not limited to a ''hazard analysis,'' as proposed in the NPRM, but provides for a broader evaluation.

Section 238.753 Sanders

This section introduces requirements for sanders on Tier III trainsets. In their comments on the NPRM, APTA and TCRR objected to inclusion of this section in the final rule. According to APTA and TCRR, in the international market, sanders are not considered a safety critical component but rather only performance enhancing and not critical to the safe operation of the trainset. Both APTA and TCRR further stated that if a railroad were to determine that sanders were critical to the safe operation of the trainset, then the sanders would be defined and addressed in the railroad's ITM program; under these circumstances, a trainset with defective sanders could move only under the regulatory provisions dealing with movement of defective equipment. Thus, APTA and TCRR believed that providing specific requirements for sanders in this section is unnecessary.

FRA disagrees with this recommendation. As explained in the NPRM, this section does not require Tier III trainsets to be equipped with sanders; this section applies only if the railroad determines sanders are a required trainset component. Some railroads may determine that sanders

are necessary for the safe operation of Tier III trainsets, whereas other railroads may not. Nonetheless, FRA agrees that if the railroad deems the sanders safety critical, they would be so identified in the railroad's ITM program. No reference to a Tier III Safe Operation Plan is necessary. Accordingly, trainsets equipped with such sanders that are defective could move only in compliance with the requirements covering movement of defective equipment. Please also see the discussion of this proposed section in the NPRM (81 FR 88006, 88038). As always, FRA will work with any proposed Tier III operation to ensure the requirements of this section are properly implemented.

Appendix A to Part 238—Schedule of Civil Penalties

The final rule includes an amended schedule of civil penalties under appendix A to this part. Specifically, the schedule includes civil penalty amounts for violations of the requirements of subpart H of this part. Because the penalty schedule is a statement of policy, notice and comment was not required prior to its revision. *See* 5 U.S.C. 553(b)(3)(A). Accordingly, FRA has amended the penalty schedule to reflect the addition of subpart H.

Appendix B to Part 238—Test Methods and Performance Criteria for the Flammability and Smoke Emission Characteristics of Materials Used in Passenger Cars and Locomotive Cabs

FRA is revising this appendix to clarify the application of the floor fire test in the table of ''Test Procedures and Performance Criteria for the Flammability and Smoke Emission Characteristics of Materials Used in Passenger Cars and Locomotive Cabs'' in paragraph (c) to Tier III passenger equipment. FRA received no comments on this clarification and has adopted it as proposed. As this portion of the final rule is identical to the proposed version, FRA is not repeating the analysis provided in the NPRM (see 81 FR 88006, 88039).

Appendix F to Part 238—Alternative Dynamic Performance Requirements for Front End Structures of Cab Cars and MU Locomotives

FRA is revising this appendix so that it applies to Tier III passenger equipment. FRA received no comments on this change and has adopted it as proposed. As this portion of the final rule is identical to the proposed version, FRA is not repeating the analysis of this change provided in the NPRM (see 81 FR 88006, 88039).

Appendix G to Part 238—Alternative Requirements for Evaluating the Crashworthiness and Occupant Protection Performance of a Tier I Passenger Trainset

As proposed, FRA is adding appendix G to this part to provide alternative crashworthiness and occupant protection performance requirements for Tier I passenger trainsets instead of the conventional requirements of §§ 238.203, 238.205, 238.207, 238.209(a), 238.211, 238.213, and 238.219 in subpart C of this part. The technical contents of appendix G remain materially unchanged from those developed for the original Technical Criteria and Procedures Report.

FRA intends for these alternative requirements to be applied to a Tier I trainset as a whole. Accordingly, compliance must be demonstrated either through application of the conventional requirements in subpart C, or through application of the requirements in this appendix G, not a combination of both. They also apply in addition to the requirements of §§ 238.209(b), 238.215, 238.217, and 238.233, and APTA standards for occupant protection, as specified in this appendix. Although the appendix may refer to specific units of rail equipment in a trainset, the alternative requirements in this appendix apply only to a Tier I trainset as a whole, as noted above. Further, use of this appendix to demonstrate alternative crashworthiness and occupant protection performance for Tier I passenger trainsets is subject to FRA review and approval under § 238.201.

In general, where alternatives to the conventional Tier I requirements are given in this appendix G, those requirements are also identified in the Tier III requirements in subpart H—Specific Requirements for Tier III Passenger Equipment. See the discussion in the section-by-section analysis for subpart H, which applies to Tier I trainsets seeking qualification under this appendix. As FRA did not receive any comments on this appendix, FRA is not repeating the full analysis of this appendix provided in the NPRM, see 81 FR 88006, 88039–88040.

However, FRA does highlight that in paragraph (i) of this appendix, FRA is incorporating by reference APTA standard PR–CS–S–034–99, Rev. 2, ''Standard for the Design and Construction of Passenger Railroad Rolling Stock,'' Authorized June 2006, for interior fixtures. The standard is intended to address forces applied to the carbody and truck structures during collisions, derailments, and other accident conditions. APTA PR–CS–S–034–99 is available to all interested parties online at *www.apta.com*. Additionally, FRA will maintain a copy available for review.

Further, in paragraph (j) of this appendix, FRA is incorporating by reference APTA standard PR–CS–S–016–99, Rev. 2, ''Standard for Passenger Seats in Passenger Rail Cars,'' Authorized October 2010, with the exception of Section 6 of the standard, which relates to the durability testing of seats. FRA considers the durability testing of seats to be beyond the scope of this final rule for the same reasons discussed under § 238.735, above.

Appendix H to Part 238—Rigid Locomotive Design Computer Model Input Data and Geometrical Depiction

FRA is adding this appendix to part 238 to formally provide input data and a geometrical depiction necessary to create a computer model of the rigid locomotive design in § 238.705(a)(4) for use in evaluating the occupied volume integrity of a Tier III trainset (and a Tier I alternative passenger trainset under appendix G) in a dynamic collision scenario. Section 238.705(a) outlines the required conditions for performing a dynamic collision scenario involving an initially-moving trainset impacting an initially-standing train having the rigid locomotive leading its consist. As explained in § 238.705(a)(4), the initially-standing train is made up of a rigid locomotive and five identical passenger coaches having the following characteristics: The locomotive weighs 260,000 pounds and each coach weighs 95,000 pounds; the locomotive and each coach crush in response to applied force as specified in Table 1 to § 238.705; and the locomotive has a geometric design as depicted in Figure 1 to this appendix H.

This appendix is intended to establish a consistent definition for locomotive geometry for use in conducting dynamic computer simulations. The input data, in the form of an input file, contains the geometry for approximately the first 12 feet of the rigid locomotive design. Because this input file is for a half-symmetric model, a locomotive mass corresponding to 130,000 pounds of weight is provided for modeling purposes—half the 260,000 pounds of weight specified for the locomotive in § 238.705(a)(4). Figure 1 to this appendix provides two views of the locomotive's geometric depiction. The input data is contained in Appendix C to FRA's Technical Criteria and Procedures Report, available at *http://www.fra.dot.gov/eLib/details/L01292#p4_z50_gD_lRT*.

VI. Regulatory Impact and Notices

A. Executive Orders 12866, 13563, and 13771, and DOT Regulatory Policies and Procedures

This final rule is an economically significant regulatory action within the meaning of Executive Order 12866 and DOT policies and procedures. *See* 44 FR 11034 (Feb. 26, 1979).

FRA has prepared and placed in the docket a Regulatory Impact Analysis (RIA) addressing the economic impacts of this final rule. The RIA estimates the costs of this final rule that are likely to be incurred over a 30-year period. FRA estimated the costs of this final rule using discount rates of 3 and 7 percent, respectively. For the 30-year period analyzed, the present value of the estimated high-range quantified net cost savings for this final rule is $837.8 million when discounted at 3 percent and $541.9 million when discounted at 7 percent. Annualized net cost savings total approximately $42.7 million when discounted at 3 percent and $43.7 million when discounted at 7 percent.

This final rule addresses several limitations in the Code of Federal Regulations pertaining to passenger equipment. Prior to publication of this final rule, the PESS in 49 CFR part 238 did not comprehensively address safety requirements for passenger rail equipment at speeds above 150 mph. Further, the regulatory framework established Tier I safety compliance through equipment requirements that were more design-based, and therefore limited the application of contemporary design techniques and innovative technology.

This final rule amends FRA's PESS and adds a new equipment tier (Tier III) to facilitate the safe implementation of high-speed rail at speeds up to 220 mph. The final rule also establishes alternative crashworthiness performance standards to qualify passenger rail equipment for Tier I operations (Tier I alternative). In addition, FRA is increasing the maximum allowable speed for Tier II operations from 150 mph to 160 mph, making it consistent with prior changes in 49 CFR parts 213 and 238 for Vehicle/Track Interaction (VTI) Safety Standards.

There are several HSR projects in development, such as Amtrak's next-generation Acela, Texas High-Speed Rail, and California's high-speed rail project, which are all expected to benefit from implementation of the rule. Additionally, FRA believes that other HSR operations may be initiated due to the publication of this final rule. The costs, cost savings, and benefits associated with the Tier III requirements of this rule were developed looking at all possible operations in the United States. FRA researched HSR projects that were most viable, focusing on all publicly available business models for HSR projects. FRA developed an economic analysis that could be applied to any individual Tier III operation in the United States, including Amtrak's next-generation Acela. The main costs savings result from minimizing the costs of right-of-way acquisition, especially in high population urban areas, such as New York, Washington, Miami, and other large metropolitan areas. The provisions of the final rule's Tier III passenger equipment safety standards allow the service to use existing rights-of-way, permitting the use of track shared with other rail service (*i.e.,* blended track).

FRA estimates that between $227.7 million and $523.3 million (when discounted at a 7-percent rate) or between $351.3 million and $808.8 million (when discounted at a 3-percent rate) in quantifiable costs will be borne by the industry over a future 30-year period in availing itself of the rule's new regulatory framework. Note that industry will only incur these costs if it chooses to test to demonstrate compliance with either the Tier I alternative, or decides to implement Tier III operations. The added alternative Tier I standards provide an option for railroads to use different types or designs of passenger equipment in Tier I service and will not impose any cost on existing rolling stock or new equipment qualifying under existing regulations. The new Tier III requirements will not impose any cost on existing rolling stock or new equipment qualifying under existing regulations (existing passenger rolling stock is Tier I and II; there is no Tier III rolling stock in operation in the U.S.).

TABLE 1—REGULATORY COST SUMMARY

[$ in millions]

Description	3%	7%
High Range: [17]		
Tier I Alternative Equipment Costs	$59.6	$39.1
Tier III Infrastructure Costs	749.2	484.2
Total Costs	808.8	523.3
Annualized Costs	*41.3*	*42.2*
Low Range: [18]		
Tier I Alternative Equipment Costs	51.6	34.1
Tier III Infrastructure Costs	299.7	193.7
Total Costs	351.3	227.7
Annualized Costs	*17.9*	*18.4*

This final rule will result in significant cost savings for the industry. Estimated infrastructure-related cost savings comprise the most significant driver of cost savings compared to other quantified cost savings (*i.e.,* equipment design and engineering, manufacturing benefits, etc.). Infrastructure cost savings will be generated by the ability of railroad operators to take advantage of a blended operating environment—avoiding costly new construction, maintenance of dedicated track, and acquisition of new rights-of-way. This

[17] High-range costs represent costs at a high funding level with a 25-percent multiplier to adjust for the upper bound confidence level of an HSR system becoming operational. For a more detailed description of the high-range costs, please refer to Section 3 of the RIA.

[18] Low-range costs represent costs at a low funding level with a 10-percent multiplier to adjust for the lower bound confidence level of an HSR system becoming operational. For a more detailed description of the low-range costs, please refer to Section 3 of the RIA.

cost savings is especially attractive to railroad operators that provide service in areas with high population density, where right-of-way acquisition and new railroad construction are significantly more expensive and complex. This rule will increase the probability that new services are introduced and reduce the need for new construction in densely populated areas.

The U.S. passenger rail industry will experience cost savings from this regulatory action because it permits manufacturers to adapt existing designs of rolling stock to meet the new standards and will allow operators to take advantage of a wider variety of trainset designs. Further, the rule will allow Tier I and Tier III operations to use service-proven platforms with the latest technology available. These cost savings will be achieved by adapting technology that exists on the international market to meet FRA's safety requirements and ensuring that all equipment suppliers comply with the same safety standards.

Table 2 provides the estimated industry equipment and infrastructure cost savings and their discounted values at the 3- and 7-percent levels, respectively. High-range cost savings represent cost savings at a high funding level with a 25-percent multiplier to adjust for the confidence level of an HSR system becoming operational. Low-range cost savings represent cost savings at a low funding level with a 10-percent multiplier to adjust for the confidence level of an HSR system becoming operational. For a more detailed description of the low- and high-range cost savings, please refer to the RIA.

TABLE 2—REGULATORY COST SAVINGS RANGE SUMMARY

[$ in millions]

Description	3%	7%
High Range:		
Tier I Alternative Equipment Cost Savings	$315.4	$205.8
Tier III Infrastructure Cost Savings	1,331.3	859.4
Total Cost Savings	1,646.7	1,065.2
Annualized Cost Savings	*84.0*	*85.8*
Low Range:		
Tier I Alternative Equipment Cost Savings	257.5	168.8
Tier III Infrastructure Cost Savings	532.5	343.7
Total Cost Savings	790.1	512.5
Annualized Cost Savings	*40.3*	*41.3*

Table 3 below displays the net cost savings of this final rule, categorized by either Tier I alternative or Tier III costs and cost savings. Discounted net regulatory cost savings will be between $438.8 million (low range) and $837.8 million (high range) at the 3-percent level, and between $284.8 million (low range) and $541.9 million (high range) at the 7-percent level. Annualized net regulatory cost savings are between $22.4 million and $42.7 million when discounted at 3 percent and between $22.9 million and $43.7 million when discounted at 7 percent.

TABLE 3—NET REGULATORY COST SAVINGS

[$ in millions]

Description	3%	7%
High Range:		
Tier I Alternative Costs	$59.6	$39.1
Tier III Costs	749.2	484.2
Total Costs	*808.8*	*523.3*
Cost Savings Tier I Alternative	315.4	205.8
Cost Savings Tier III	1,331.3	859.4
Total Cost Savings	*1,646.7*	*1,065.2*
Net Cost Savings Tier I Alternative	255.8	166.7
Net Cost Savings Tier III	582.1	375.2
Total Net Cost Savings	*837.8*	*541.9*
Annualized Net Cost Savings	42.7	43.7
Low Range:		
Tier I Alternative Costs	51.6	34.1
Tier III Costs	299.7	193.7
Total Costs	*351.3*	*227.7*
Cost Savings Tier I Alternative	257.5	168.8
Cost Savings Tier III	532.5	343.7
Total Cost Savings	*790.1*	*512.5*
Net Cost Savings Tier I Alternative	205.9	134.7

TABLE 3—NET REGULATORY COST SAVINGS—Continued

[$ in millions]

Description	3%	7%
Net Cost Savings Tier III	232.8	150.1
Total Net Cost Savings	*438.8*	*284.8*
Annualized Net Cost Savings	22.4	22.9

This final rule is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in the RIA.

B. Regulatory Flexibility Act and Executive Order 13272

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally requires an agency to prepare a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. Small entities include small businesses, small organizations, and governmental jurisdictions. An agency must conduct a regulatory flexibility analysis unless it determines and certifies that the rule is not expected to have a significant economic impact on a substantial number of small entities. FRA developed this final rule in accordance with Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure potential impacts of rules on small entities are properly considered.

Prior to this final rule, the Passenger Equipment Safety Standards in part 238 did not comprehensively address safety requirements for passenger rail equipment at speeds above 150 mph. Further, the former regulatory framework generally set Tier I safety compliance through equipment design requirements, which limited the application of new technology. This final rule changes the passenger rail equipment safety regulatory framework by introducing a new tier of equipment safety standards (Tier III) and also establishes more performance-based crashworthiness and occupant protection requirements in the alternative to those specified for Tier I equipment. Additionally, the final rule increases the maximum allowable speed for Tier II equipment to make it consistent the corresponding speed range in FRA's Track Safety Standards for the track over which the equipment operates. This Final Regulatory Flexibility Analysis is presented to comply with Executive Order 13272 and with the Regulatory Flexibility Act as part of the rulemaking process required by law.

FRA initiated the rulemaking using recommendations made by FRA's RSAC. In general, the rulemaking amends 49 CFR part 238, to reflect new or modified safety requirements for Tier I and Tier III equipment, and to increase the authorized speed limit for Tier II equipment.

1. Description of Regulated Entities and Impacts

The ''universe'' of the entities under consideration includes only those small entities that can reasonably be expected to be directly affected by the provisions of this final rule. For the rule, there is only one type of small entity that will be affected: Small passenger railroads. ''Small entity'' is defined in 5 U.S.C. 601(3) as having the same meaning as ''small business concern'' under section 3 of the Small Business Act. This includes any small business concern that is independently owned and operated, and is not dominant in its field of operation. Under 5 U.S.C. 601(5) ''small entities'' is defined as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000.

The U.S. Small Business Administration (SBA) stipulates ''size standards'' for small entities. It provides that industry sectors relevant for the rulemaking must not exceed the limits listed below (and still classify as a ''small entity''): [19]

- 1,500 employees for railroad rolling stock manufacturing.
- 1,500 employees for line haul operating railroads.
- 1,250 employees for motor and generator manufacturing.
- 1,250 employees for switchgear and switchboard apparatus manufacturing.

Federal agencies may adopt their own size standards for small entities in consultation with SBA, and in conjunction with public comment. Under the authority provided to it by SBA, FRA published a final policy, which formally establishes small entities as railroads that meet the line haulage revenue requirements of a Class III railroad.[20] Currently, the revenue requirements are $20 million or less in annual operating revenue, adjusted annually for inflation. The $20 million limit (adjusted annually for inflation) is based on the Surface Transportation Board's threshold of a Class III railroad, which is adjusted by applying the railroad revenue deflator adjustment.[21] FRA uses this definition for the rule.

Railroads

For purposes of this analysis, there are only two intercity passenger railroads, Amtrak and the Alaska Railroad. Neither is considered a small entity. Amtrak is a Class I railroad and the Alaska Railroad is a Class II railroad. The Alaska Railroad is owned by the State of Alaska, which has a population well in excess of 50,000. There are currently 30 commuter or other short-haul passenger railroad operations in the U.S., most of which are part of larger transportation organizations that receive Federal funds and serve major metropolitan areas with populations greater than 50,000. However, one of these railroads does not fall in this category and is considered a small entity: The Hawkeye Express. The Hawkeye Express provides service to Iowa City, Iowa, and is owned by a Class III railroad, a small entity. FRA notes that it has not analyzed the Saratoga & North Creek Railway as a small entity under this final rule. Because of operational changes subsequent to the NPRM's publication, FRA considers the Saratoga & North Creek Railway a tourist railroad, not subject to this rule.

[19] U.S. Small Business Administration, ''Table of Small Business Standards Matched to North American Industry Classification System Codes,'' effective January 1, 2018.

[20] *See* 68 FR 24891, May 9, 2003.

[21] For further information on the calculation of the specific dollar limit, please see 49 CFR part 1201.

It is important to note that the small railroad being considered in this analysis uses passenger rolling stock that is different from the equipment covered by the rulemaking. Further, the Hawkeye Express would be able to find their current type of train equipment in the market if they decide to acquire new rolling stock over the next 30 years. This final rule does not increase costs for this small passenger railroad. FRA expects the cost to acquire passenger rail equipment will drop as a result of the rulemaking. There will be more variety in trainset models available for passenger operations and options in companies supplying equipment in the U.S. market. Additionally, the railroad may enjoy lower prices as the U.S. passenger rail market is enlarged as a result of the rulemaking, enhancing economies of scale and increasing predictability for equipment orders.

Passenger Railroad Rolling Stock Manufacturing

The passenger rail and urban rapid transit equipment manufacturing sector in the United States has a fairly small number of firms with no more than 15 Original Equipment Manufacturers (OEM) and a few hundred component and subcomponent suppliers.[22] However, for this flexibility analysis, FRA is taking a broader approach by assessing the effect of the regulation on the railroad rolling stock manufacturing sector as defined by the North American Classification System (NAICS), which includes the passenger rail and urban rapid transit equipment manufacturing industry but goes beyond by also covering freight and maintenance-of-way vehicles. This approach includes firms that currently do not manufacture passenger rail equipment but can potentially enter the market. Based on data from the U.S. Census Bureau, employment in these industries is as follows:

- NAICS code 336510, Railroad rolling stock manufacturing, 159 firms in the industry, and 137 firms with less than 500 employees.
- NAICS code 335312, Motor and generator manufacturing, 428 firms in the industry, and 384 firms with less than 500 employees.

The main impact of the rule affecting these industries is the qualification costs for Tier I alternative and Tier III trainsets. FRA worked with the industry to develop new safety criteria to evaluate passenger equipment designed to standards differing from those historically used for procurements in the U.S. As noted in the RIA, companies supplying new trainsets covered by the rulemaking will be required to submit test and analysis results to demonstrate compliance with these new safety standards. However, in the case of rolling stock manufacturing, this cost will only be incurred by the OEM when submitting a qualification package, which would include details regarding the performance of the trainset model under the required tests and analyses. Therefore, small and very small firms supplying OEMs are not expected to be required to submit that information. Small firms could be expected to benefit from existing requirements for minimum domestic content as more trainsets are purchased by U.S. railroad operators. Small businesses have the opportunity to supply OEMs with domestic inputs and to partner with larger firms to allow small domestic producers to meet the needs of the market being created by this final rule. Consequently, FRA expects the rulemaking to have only a positive impact on these small entities as more of them are provided with the opportunity to enter the passenger railroad equipment manufacturing industry.

Significant Economic Impact Criteria

Previously, FRA sampled small railroads and found that revenue averaged approximately $4.7 million (not discounted) in 2006. One percent of average annual revenue per small railroad is $47,000. FRA realizes that some railroads will have revenue lower than $4.7 million. However, FRA estimates that small railroads will not have any additional expenses over the next ten years to comply with the requirements in this rule. Based on this, FRA concludes that the expected burden of this rule will not have a significant impact on the competitive position of small entities, or on the small entity segment of the railroad industry as a whole.

Substantial Number Criteria

This final rule will likely affect any small railroad that is not exempt from its scope or application (see 49 CFR 238.3). Thus, as noted above, this final rule will impact a substantial number of small railroads.

2. Certification

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Administrator of the Federal Railroad Administration certifies that this rule will not have a significant economic impact on a substantial number of small entities. In the NPRM, FRA requested comments on its certification made as a result of its Regulatory Flexibility Act analysis, see 81 FR 88006, 88044. FRA received no comments. FRA therefore stands with its previous Regulatory Flexibility Act certification.

C. Paperwork Reduction Act

The information collection requirements in this final rule are being submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The sections that contain the new, revised, and current information collection requirements and the estimated time to fulfill each requirement are as follows:

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
229.47—Emergency Brake Valve—Marking brake pipe valve as such	32 railroads	32 markings	1 minute	1
238.7—Waivers	32 railroads	5 waivers	2 hours	10
238.15—Movement of passenger equipment with power brake defect	32 railroads	1,000 tags	3 minutes	50
—Movement of passenger equipment—defective en route	32 railroads	288 tags	3 minutes	14
—Conditional requirement—Notice	32 railroads	144 notices	3 minutes	7
238.17—Limitations on movement of passenger equipment—defects found at calendar day insp. & on movement of passenger equipment—develops defects en route.	32 railroads	200 tags	3 minutes	10
—Special requirements—movement of passenger equip. with safety appliance defect.	32 railroads	76 tags	3 minutes	4
—Crew member notifications	32 railroads	38 radio notifications	30 secs	.32
238.21—Petitions for special approval of alternative standards	32 railroads	1 petition	16 hours	16

[22] Lowe, M., Tokuoka, S., Dubay, K., and Gereffi, G., ''U.S. Manufacture of Rail Vehicles for Intercity Passenger Rail and Urban Transit: A Value Chain Analysis,'' Center on Globalization, Governance & Competitiveness, June 24, 2010.

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
—Petitions for special approval of pre-revenue service acceptance testing plan	32 railroads	1 petition	40 hours	40
—Comments on petitions	Public/RR Industry	4 comments	1 hour	4
238.103—Fire Safety:				
—Procuring new pass. equipment—Fire Safety Analysis	2 new railroads	1 analysis	150 hours	150
—Transferring existing equipment—Revised Fire Safety Analysis	32 railroads/APTA	3 analyses	20 hours	60
238.107—Inspection/testing/maintenance plans—RR review	32 railroads	32 reviews	60 hours	1,920
238.109—Employee/Contractor Tr.:				
—Training employees—Mech. insp	7,500 employees/100 trainers.	2,500 empl./100 trainers.	1.33 hours	3,458
—Recordkeeping—Employee/Contractor current qualifications	32 railroads	2,500 records	3 minutes	125
238.111—Pre-revenue service acceptance testing plan: Passenger equipment that has previously been used in service in the U.S.	9 equipment manufacturers.	1 plan	16 hours	16
—Passenger equipment that has not been previously used in revenue service in the U.S.	9 equipment manufacturers.	1 plan	192 hours	192
—Subsequent equipment orders	9 equipment manufacturers.	1 plan	60 hours	60
—Tier II & Tier III Passenger Equipment: Report of test results to FRA (Revised Requirement).	32 railroads	1 report	60 hours	60
—Plan submitted to FRA for Tier II or Tier III equipment before being placed in service (Revised Requirement).	32 railroads	1 plan	20 hours	20
238.131—Exterior side door safety systems—new passenger cars/locomotives used in passenger service: Failure Modes, Effects, Criticality Analysis (FMECA).	6 passenger car builders.	2 analyses	4 hours	8
238.133—Exterior side door safety systems—passenger cars/locomotives used in passenger service: Functional test plans.	32 railroads	32 plan updates	4 hours	128
—Notification to designated RR authority by train crewmember of unsealed door by-pass device.	32 railroads	9,994 radio notifications.	30 secs	84
—Safety briefing by train crew when door by-pass device is activated	32 railroads	320 safety briefings	2 minutes	11
—Notification to designated RR authority by train crewmember that door by-pass device has been activated.	32 railroads	320 radio notifications	30 secs	3
—On-site qualified person (QP) description to a qualified maintenance person (QMP) off-site that equipment is safe to move for repairs.	32 railroads	320 QP descriptions	5 minutes	27
—QP/QMP notification to crewmember in charge that door by-pass has been activated + safety briefing by train crew.	32 railroads	320 notices + 320 safety briefings.	30 seconds + 10 min.	56
—RR record of each door by-pass activation	32 railroads	320 records	2 minutes	11
—RR record of unintended power door openings	32 railroads	20 records	2 hours	40
—RR record of by-pass activations found unsealed	32 railroads	20 records	4 hours	80
238.135—RR request to FRA for special consideration to operate passenger trains with exterior side doors or trap doors, or both, open between stations.	32 railroads	2 requests	25 hours	50
—FRA request to RR for additional information concerning special consideration request.	32 railroads	1 additional document	12 hours	12
—RR Operating rule to override a door summary circuit or no motion system, or both, in the event of an en route exterior side door failure or malfunction on a passenger train.	32 railroads	10 operating rules	42 hours	420
—RR copy of written operating rules to train crew members and control center personnel.	32 railroads	10,000 op. rule copies	1 minute	167
—RR training of train crew members on requirements of this section	32 railroads	3,383 RR trained employees.	30 mins	1,692
—RR training of new employees	32 railroads	150 workers	30 mins	75
—RR operational/efficiency tests of train crew members & control center employees	32 railroads	3,383 tests	2 minutes	113
238.201—New Requirements—Alternative Compliance: Tier I Passenger equipment—Test plans + supporting documentation demonstrating compliance.	32 railroads	1 plan	40 hours	40
—Notice of tests sent to FRA 30 days prior to commencement of operations	32 railroads	1 notice	30 mins	1
238.229—Safety Appliances:				
—Welded safety appliances: Lists	32 railroads	32 lists	1 hour	32
—Defective welded safety appliance—Tags	32 railroads	4 tags	3 minutes	.20
—Notification to crewmembers about non-compliant equipment	32 railroads	2 notices	1 minute	.0333
—Inspection plans				
—Inspection personnel—Training	32 railroads	1 plan	16 hours	16
—Remedial action: Defect/crack in weld—record	32 railroads	60 workers	4 hours	240
	32 railroads	1 record	2.25 hours	2
—Petitions for special approval of alternative compliance—impractical equipment design.	32 railroads	1 petition	4 hours	4
—Records of inspection/repair of welded safety appliance brackets/supports/training	32 railroads	3,264 records	12 mins	653
238.230—Safety Appliances—New Equipment—Inspection record of welded equipment by qualified Employee.	32 railroads	100 records	6 minutes	10
—Welded safety appliances: Documentation for equipment impractically designed to mechanically fasten safety appliance support.	32 railroads	1 document	4 hours	4
238.231—Brake System—Inspection and repair of hand/parking brake: Records	32 railroads	2,500 forms	21 mins	875
—Procedures verifying hold of hand/parking brakes	32 railroads	1 procedure	2 hours	2
238.237—Automated monitoring:				
—Documentation for alerter/deadman control timing	32 railroads	1 document	2 hours	2
—Defective alerter/deadman control: Tagging	32 railroads	25 tags	3 minutes	1
238.303—Exterior calendar day mechanical inspection of passenger equipment: Notice of previous inspection.	32 railroads	32 notices	1 minute	1
—Dynamic brakes not in operating mode: Tag	32 railroads	50 tags	3 minutes	3
—Conventional locomotives equipped with inoperative dynamic brakes: Tagging	32 railroads	50 tags	3 minutes	3
—MU passenger equipment found with inoperative/ineffective air compressors at exterior calendar day inspection: Documents.	32 railroads	4 documents	2 hours	8
—Written notice to train crew about inoperative/ineffective air compressors	32 railroads	100 notices	3 minutes	5

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
—Records of inoperative air compressors	32 railroads	100 records	2 minutes	3
—Record of exterior calendar day mechanical inspection	32 railroads	1,959,620 records	10 minutes + 1 minute.	359,264
238.305—Interior calendar day mechanical inspection of passenger cars—Tagging of defective end/side doors.	32 railroads	540 tags	1 minute	9
—Records of interior calendar day inspection	32 railroads	1,959,620 records	5 minutes + 1 minute.	359,264
238.307—Periodic mechanical inspection of passenger cars and unpowered vehicles—Alternative inspection intervals: Notifications.	32 railroads	2 notices/notifications	5 hours	10
—Notice of seats/seat attachments broken or loose	32 railroads	200 notices	2 minutes	7
—Records of each periodic mechanical inspection	32 railroads	19,284 insp./records	200 hours/ 2 minutes.	3,857,443
—Detailed documentation of reliability assessments as basis for alternative inspection interval.	32 railroads	5 documents	100 hours	500
238.311—Single car test:				
—Tagging to indicate need for single car test	32 railroads	50 tags	3 minutes	3
238.313—Class I Brake Test:				
—Record for additional inspection for passenger equipment that does not comply with § 238.231(b)(1).	32 railroads	15,600 insp./records	30 minutes	7,800
238.315—Class IA brake test:				
—Notice to train crew that test has been performed (verbal notice)	32 railroads	18,250 notices	5 seconds	25
—Communicating signal tested and operating as intended	32 railroads	365,000 op. sufficiency tests.	15 seconds.	1,521
238.317—Class II brake test:				
—Communicating signal tested and operating as intended	32 railroads	365,000 op. sufficiency tests.	15 seconds.	1,521
238.321—Out-of-service credit—Passenger car: Out-of-use notation	32 railroads	1,250 notes	2 minutes	42
238.445—Automated Monitoring:				
—Performance monitoring: Alerters/alarms	1 railroad	10,000 alerts/alarms	10 secs	28
—Monitoring system: Self-test feature: Notifications	1 railroad	21,900 notices	20 secs	122
238.703—Quasi-static Load Requirements—Document/analysis for Tier III Trainsets showing compliance with this section (*New Requirement*).	2 railroads	1 analysis	40 hours	40
238.705—Dynamic Collision Scenario—Demonstration of Occupied Volume Integrity for Tier III Trainsets—Model validation document (*New Requirement*).	2 railroads	1 model validation/ analysis.	40 hours	40
238.707—Override Protection—Anti-climbing performance test/analysis for Tier III Trainsets (*New Requirement*).	2 railroads	1 test/analysis	40 hours	40
238.709—Fluid Entry Inhibition—Information to demonstrate compliance with this section—Tier III Trainsets (*New Requirement*).	2 railroads	1 compliance document/analysis.	20 hours	20
238.721—*New Requirements*—Tier III Trainsets—End-facing document/analysis for exterior windows of Tier III Trainsets.	5 glass manufacturers.	1 data document/analysis.	60 hours	60
—Marking of End-facing exterior windows Tier III Trainsets	5 glass manuf	60 markings	2 minutes	2
—Cab Glazing; Side-facing exterior windows in Tier III cab—document showing compliance with Type II glazing.	5 glass manuf	1 document analysis	10 hours	10
—Marking of side-facing exterior windows in Tier III Trainsets	5 glass manuf	120 window markings	2 minutes	4
—Non-Cab Glazing; Side-facing exterior windows—Tier III—compliance document for Type II glazing.	5 glass manuf	1 data document/analysis.	20 hours	20
—Marking of side-facing exterior windows—Tier III Trainsets—non-cab cars	5 glass manuf	1, 200 glass markings	2 minutes	40
—Alternative standard to FRA for side-facing exterior window intended to be breakable and serve as an emergency window exit (option to comply with an alternative standard).	5 glass manuf	1 alternative standard	5 hours	5
238.731—*New Requirements*—Brake Systems—RR analysis and testing Tier III trainsets' maximum safe operating speed.	2 railroads	1 analysis/test	480 hours	480
—Tier III trainsets' passenger brake alarm—legible stenciling/marking of devices with words ''Passenger Brake Alarm''.	2 railroads	240 stencils/markings	20 minutes	80
—Main reservoir test/certification	2 railroads	1 test/cert	6 hours	6
—Inspection, testing and maintenance plan (ITM)—Periodic inspection for main reservoirs.	2 railroads	1 ITM plan	480 hours	480
—Brake actuator design with approved brake cylinder pressure as part of design review process.	2 railroads	1 design	40 hours	40
—Tier III equipment: Demonstrated securement procedure	2 railroads	1 procedure	8 hours	8
238.733—Tier III Interior fixture attachment standard—analysis for FRA approval (*New Requirement*).	2 railroads	1 analysis/document	20 hours	20
238.735—Tier III seat crashworthiness standard (passenger & cab crew)—analysis for FRA approval (New Requirement).	2 railroads	1 analysis/document	40 hours	40
238.737—Tier III luggage racks standard—analysis for FRA approval (New Requirement).	2 railroads	1 analysis/document	20 hours	20
238.741—New Requirement—Emergency window egress/rescue plan to FRA for passenger cars in Tier III trainsets not in compliance with sections 238.113 or 238.114.	2 railroads	1 plan	60 hours	60
238.743—*New Requirement*—Emergency Lighting Std.—Tier III trainsets—analysis/test	2 railroads	1 analysis/test	60 hours	60
238.751—*New Requirements*—Alerters—alternate technology- Tier III trainsets—analysis/test.	2 railroads	1 analysis/test	40 hours	40

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the information collection submission sent to OMB, please contact FRA Information Collection Clearance Officers Mr. Robert Brogan at (202) 493–6292 or Ms. Kimberly Toone at (202) 493–6132, or via email at the following addresses: *Robert.Brogan@dot.gov; Kimberly.Toone@dot.gov*.

Organizations and individuals desiring to submit comments on the collection of information requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th St. NW, Washington, DC 20503, attn: FRA Desk Officer. Comments may also be sent via email to the Office of Management and Budget at the following address: *oira_submissions@omb.eop.gov*.

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

FRA cannot impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. FRA intends to obtain current OMB control numbers for any new information collection requirements resulting from this rulemaking action prior to the effective date of this final rule. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register**.

D. Federalism Implications

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), requires FRA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' are defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with federalism implications that imposes substantial direct compliance costs and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or the agency consults with State and local government officials early in the process of developing the regulation. Where a regulation has federalism implications and preempts State law, the agency seeks to consult with State and local officials in the process of developing the regulation.

This final rule has been analyzed under the principles and criteria contained in Executive Order 13132. This final rule will not have a substantial effect on the States or their political subdivisions, and it will not affect the relationships between the Federal government and the States or their political subdivisions, or the distribution of power and responsibilities among the various levels of government. In addition, FRA has determined that this regulatory action will not impose substantial direct compliance costs on the States or their political subdivisions. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

However, this final rule could have preemptive effect by operation of law under certain provisions of the Federal railroad safety statutes, specifically the former Federal Railroad Safety Act of 1970, repealed and recodified at 49 U.S.C. 20106, and the former Locomotive Boiler Inspection Act (LIA) at 45 U.S.C. 22–34, repealed and re-codified at 49 U.S.C. 20701–20703. Section 20106 provides that States may not adopt or continue in effect any law, regulation, or order related to railroad safety or security that covers the subject matter of a regulation prescribed or order issued by the Secretary of Transportation (with respect to railroad safety matters) or the Secretary of Homeland Security (with respect to railroad security matters), except when the State law, regulation, or order qualifies under the ''essentially local safety or security hazard'' exception to section 20106. Moreover, the former LIA has been interpreted by the Supreme Court as preempting the field concerning locomotive safety. *See Napier* v. *Atlantic Coast Line R.R.,* 272 U.S. 605 (1926).

E. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39, 19 U.S.C. 2501 *et seq.*) prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

FRA has assessed the potential effect of this rulemaking on foreign commerce and believes that its requirements are consistent with the Trade Agreements Act. The requirements are safety standards, which, as noted, are not considered unnecessary obstacles to trade. Moreover, FRA has sought, to the extent practicable, to state the requirements in terms of the performance desired, rather than in more narrow terms restricted to a particular design or system.

F. Environmental Impact

FRA has evaluated this final rule in accordance with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), other environmental statutes, related regulatory requirements, and its ''Procedures for Considering Environmental Impacts'' (FRA's Procedures) (64 FR 28545, May 26, 1999). FRA has determined that this final rule is categorically excluded from detailed environmental review pursuant to section 4(c)(20) of FRA's Procedures, which concerns the promulgation of railroad safety rules and policy statements that do not result in significantly increased emissions of air or water pollutants or noise or increased traffic congestion in any mode of transportation. *See* 64 FR 28547, May 26, 1999. Categorical exclusions (CEs) are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). *See* 40 CFR 1508.4.

In analyzing the applicability of a CE, the agency must also consider whether extraordinary circumstances are present that would warrant a more detailed environmental review through the preparation of an EA or EIS. Id. In accordance with section 4(c) and (e) of FRA's Procedures, the agency has further concluded that no extraordinary circumstances exist with respect to this regulation that might trigger the need for a more detailed environmental review. The purpose of this rulemaking is to amend FRA's Passenger Equipment Safety Standards. This rulemaking adds safety standards to facilitate the safe implementation of high-speed rail at

speeds up to 220 mph (Tier III). The rule also establishes crashworthiness and occupant protection performance requirements in the alternative to those specified for passenger trainsets operated at speeds up to 125 mph (Tier I). In addition, the rule increases from 150 mph to 160 mph the maximum speed allowable for the tier of railroad passenger equipment currently operated at the Nation's highest train speeds (Tier II). FRA does not anticipate any environmental impacts from the requirements and finds that there are no extraordinary circumstances present in connection with this final rule.

G. Executive Order 12898 (Environmental Justice)

Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' and DOT Order 5610.2(a) (91 FR 27534, May 10, 2012) require DOT agencies to achieve environmental justice as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority populations and low-income populations. The DOT Order instructs DOT agencies to address compliance with Executive Order 12898 and requirements within the DOT Order in rulemaking activities, as appropriate. FRA has evaluated this rule under Executive Order 12898 and the DOT Order and has determined that it will not cause disproportionately high and adverse human health and environmental effects on minority populations or low-income populations.

H. Executive Order 13175 (Tribal Consultation)

FRA has evaluated this rule in accordance with the principles and criteria contained in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' dated November 6, 2000. This rule will not have a substantial direct effect on one or more Indian tribes, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal laws. Therefore, the funding and consultation requirements of Executive Order 13175 do not apply, and a tribal summary impact statement is not required.

I. Unfunded Mandates Reform Act of 1995

Under section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency ''shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law).'' Section 202 of the Act (2 U.S.C. 1532) further requires that ''before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement'' detailing the effect on State, local, and tribal governments and the private sector. This final rule will not result in the expenditure, in the aggregate, of $100,000,000 or more (as adjusted annually for inflation) in any one year, and thus preparation of such a statement is not required.

J. Energy Impact

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' requires Federal agencies to prepare a Statement of Energy Effects for any ''significant energy action.'' *See* 66 FR 28355, May 22, 2001. FRA has evaluated this final rule in accordance with Executive Order 13211 and determined that this regulatory action is not a ''significant energy action'' within the meaning of the Executive Order.

Executive Order 13783, ''Promoting Energy Independence and Economic Growth,'' requires Federal agencies to review regulations to determine whether they potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources. *See* 82 FR 16093, March 31, 2017. FRA has determined this regulatory action will not burden the development or use of domestically produced energy resources.

K. Analysis Under 1 CFR Part 51

As required by 1 CFR 51.5, FRA has summarized the standards it is incorporating by reference and shown the reasonable availability of those standards in the section-by-section analysis of §§ 238.733, 238.735, 238.737, 238.743, and Appendix G, paragraphs (i) and (j) of this rulemaking document.

List of Subjects

49 CFR Parts 229, 231, and 236

Railroad safety.

49 CFR Part 238

Incorporation by reference, Passenger equipment, Railroad safety, Reporting and recordkeeping requirements.

The Rule

For the reasons discussed in the preamble, FRA amends parts 229, 231, 236, and 238 of chapter II, subtitle B of title 49, Code of Federal Regulations as follows:

PART 229—[AMENDED]

■ 1. The authority citation for part 229 continues to read as follows:

Authority: 49 U.S.C. 103, 322(a), 20103, 20107, 20901–02, 21301, 21302, 21311; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

■ 2. Revise § 229.3(c) to read as follows:

§ 229.3 Applicability.

* * * * *

(c) Paragraphs (a) and (b) of § 229.125 do not apply to Tier II passenger equipment as defined in § 238.5 of this chapter (*i.e.,* passenger equipment operating at speeds exceeding 125 mph but not exceeding 160 mph).

* * * * *

■ 3. Section 229.5 is amended by revising the definition of ''Tier II'' to read as follows:

§ 229.5 Definitions.

* * * * *

Tier II means operating at speeds exceeding 125 mph but not exceeding 160 mph.

* * * * *

PART 231—[AMENDED]

■ 4. The authority citation for part 231 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20131, 20301–20303, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

■ 5. Revise § 231.0(c) to read as follows:

§ 231.0 Applicability and penalties.

* * * * *

(c) Except for the provisions governing uncoupling devices, this part does not apply to Tier II passenger equipment as defined in § 238.5 of this chapter (*i.e.,* passenger equipment operating at speeds exceeding 125 mph but not exceeding 160 mph).

* * * * *

PART 236—[AMENDED]

■ 6. The authority citation for part 236 continues to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20157, 20301–20303, 20306, 20701–20703, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart I—Positive Train Control Systems

§ 236.1007 [Amended]

■ 7. In § 236.1007, remove paragraph (d), and redesignate paragraph (e) as new paragraph (d).

PART 238—[AMENDED]

■ 8. The authority citation for part 238 continues to read as follows:

Authority: 49 U.S.C. 20103, 20107, 20133, 20141, 20302–20303, 20306, 20701–20702, 21301–21302, 21304; 28 U.S.C. 2461, note; and 49 CFR 1.89.

Subpart A—General

■ 9. Section 238.5 is amended by:
■ a. Adding in alphabetical order a definition of ''Associate Administrator'';
■ b. Revising the definitions of ''glazing, end-facing'', ''glazing, side-facing'', and ''Tier II'';
■ c. Adding in alphabetical order a definition of ''Tier III'';
■ d. Revising the definition of ''Train, Tier II passenger''; and
■ e. Adding in alphabetical order definitions of ''Trainset, Tier I alternative passenger'', ''Trainset, Tier III'', and ''Trainset unit''.

The additions and revisions read as follows:

§ 238.5 Definitions.

* * * * *

Associate Administrator means Associate Administrator for Railroad Safety and Chief Safety Officer, Associate Administrator for Railroad Safety, Associate Administrator for Safety.

* * * * *

Glazing, end-facing means any exterior glazing located where a line perpendicular to the plane of the glazing material makes a horizontal angle of 50 degrees or less with the centerline of the vehicle in which the glazing material is installed, except for: The coupled ends of multiple-unit (MU) locomotives or other equipment semi-permanently connected to each other in a train consist; and end doors of passenger cars at locations other than the cab end of a cab car or MU locomotive. Any location which, due to curvature of the glazing material, can meet the criteria for either an end-facing glazing location or a side-facing glazing location shall be considered an end-facing glazing location.

* * * * *

Glazing, side-facing means any glazing located where a line perpendicular to the plane of the glazing material makes a horizontal angle of more than 50 degrees with the centerline of the vehicle in which the glazing material is installed. Side-facing glazing also means glazing located at the coupled ends of MU locomotives or other equipment semi-permanently connected to each other in a train consist and glazing located at end doors other than at the cab end of a cab car or MU locomotive.

* * * * *

Tier II means operating at speeds exceeding 125 mph but not exceeding 160 mph.

Tier III means operating in a shared right-of-way at speeds not exceeding 125 mph and in an exclusive right-of-way without grade crossings at speeds exceeding 125 mph but not exceeding 220 mph.

* * * * *

Train, Tier II passenger means a short-distance or long-distance intercity passenger train providing service at speeds exceeding 125 mph but not exceeding 160 mph.

* * * * *

Trainset, Tier I alternative passenger means a trainset consisting of Tier I passenger equipment demonstrating alternative crashworthiness and occupant protection performance under the requirements of appendix G to this part.

Trainset, Tier III means an intercity passenger train that provides service in a shared right-of-way at speeds not exceeding 125 mph and in an exclusive right-of-way without grade crossings at speeds exceeding 125 mph but not exceeding 220 mph.

Trainset unit means a trainset segment located between connecting arrangements (articulations).

* * * * *

■ 10. In § 238.21 revise paragraphs (c)(2) and (d)(2) to read as follows:

§ 238.21 Special approval procedure.

* * * * *

(c) * * *

(2) The elements prescribed in §§ 238.201(b)(1), 238.229(j)(2), and 238.230(d); and

* * * * *

(d) * * *

(2) Each petition for special approval of the pre-revenue service acceptance testing plan shall be submitted to the Associate Administrator, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

* * * * *

Subpart B—Safety Planning and General Requirements

■ 11. In § 238.111 revise paragraphs (b)(2), (4), (5), and (7), and (c) to read as follows:

§ 238.111 Pre-revenue service acceptance testing plan.

* * * * *

(b) * * *

(2) Submit a copy of the plan to FRA at least 30 days before testing the equipment and include with that submission notification of the times and places of the pre-revenue service tests to permit FRA observation of such tests. For Tier II and Tier III passenger equipment, the railroad shall obtain FRA approval of the plan under the procedures specified in § 238.21.

* * * * *

(4) Document in writing the results of the tests. For Tier II and Tier III passenger equipment, the railroad shall report the results of the tests to the Associate Administrator at least 90 days prior to its intended operation of the equipment in revenue service.

(5) Correct any safety deficiencies identified in the design of the equipment or in the ITM procedures uncovered during testing. If safety deficiencies cannot be corrected by design changes, the railroad shall impose operational limitations on the revenue service operation of the equipment designed to ensure the equipment can operate safely. For Tier II and Tier III passenger equipment, the railroad shall comply with any operational limitations the Associate Administrator imposes on the revenue service operation of the equipment for cause stated following FRA review of the results of the test program. This section does not restrict a railroad from petitioning FRA for a waiver of a safety regulation under the procedures specified in part 211 of this chapter.

* * * * *

(7) For Tier II or Tier III passenger equipment, obtain approval from the Associate Administrator before placing the equipment in revenue service. The Associate Administrator will grant such approval if the railroad demonstrates compliance with the applicable requirements of this part.

(c) If a railroad plans a major upgrade or introduction of new technology to Tier II or Tier III passenger equipment that has been used in revenue service in

the United States and that affects a safety system on such equipment, the railroad shall follow the procedures in paragraph (b) of this section before placing the equipment in revenue service with the major upgrade or introduction of new technology.

Subpart C—Specific Requirements for Tier I Passenger Equipment

■ 12. In § 238.201, redesignate the text after the heading of paragraph (b) as paragraph (b)(1), revise the first sentence of newly redesignated paragraph (b)(1), and add paragraph (b)(2) to read as follows:

§ 238.201 Scope/alternative compliance.

* * * * *

(b) * * * (1) Passenger equipment of special design shall be deemed to comply with this subpart, other than § 238.203, for the service environment the petitioner proposes to operate the equipment in if the Associate Administrator determines under paragraph (c) of this section that the equipment provides at least an equivalent level of safety in such environment for the protection of its occupants from serious injury in the case of a derailment or collision. * * *

(2)(i) Tier I passenger trainsets may comply with the alternative crashworthiness and occupant protection requirements in appendix G to this part instead of the requirements in §§ 238.203, 238.205, 238.207, 238.209(a), 238.211, 238.213, and 238.219.

(ii) To assess compliance with the alternative requirements, the railroad shall submit the following documents to the Associate Administrator, for review:

(A) Test plans, and supporting documentation for all tests intended to demonstrate compliance with the alternative requirements and to validate any computer modeling and analysis used, including notice of such tests, 30 days before commencing the tests; and

(B) A carbody crashworthiness and occupant protection compliance report based on the analysis, calculations, and test data necessary to demonstrate compliance.

(iii) The carbody crashworthiness and occupant protection compliance report shall be deemed acceptable unless the Associate Administrator stays action by written notice to the railroad within 60 days after receipt of the report.

(A) If the Associate Administrator stays action, the railroad shall correct any deficiencies FRA identified and notify FRA it has corrected the deficiencies before placing the subject equipment into service.

(B) FRA may also impose written conditions necessary for safely operating the equipment, for cause stated.

* * * * *

■ 13. Revise § 238.203(a)(1) to read as follows:

§ 238.203 Static end strength.

(a)(1) Except as further specified in this paragraph (a), paragraph (d) of this section, and § 238.201(b)(2), on or after November 8, 1999, all passenger equipment shall resist a minimum static end load of 800,000 pounds applied on the line of draft without permanent deformation of the body structure.

* * * * *

■ 14. Revise the first sentence of § 238.205(a) to read as follows:

§ 238.205 Anti-climbing mechanism.

(a) Except as provided in paragraph (b) of this section, and § 238.201(b), all passenger equipment placed in service for the first time on or after September 8, 2000, and prior to March 9, 2010, shall have at both the forward and rear ends an anti-climbing mechanism capable of resisting an upward or downward vertical force of 100,000 pounds without failure. * * *

* * * * *

■ 15. Revise § 238.207 to read as follows:

§ 238.207 Link between coupling mechanism and carbody.

Except as specified in § 238.201(b), all passenger equipment placed in service for the first time on or after September 8, 2000, shall have a coupler carrier at each end designed to resist a vertical downward thrust from the coupler shank of 100,000 pounds for any normal horizontal position of the coupler, without permanent deformation. Passenger equipment connected by articulated joints that complies with the requirements of § 238.205(a) also complies with the requirements of this section.

■ 16. Amend § 238.209 by adding paragraph (a) introductory text to read as follows:

§ 238.209 Forward end structure of locomotives, including cab cars and MU locomotives.

(a) Except as specified in § 238.201(b)—

* * * * *

■ 17. Revise § 238.211(a) introductory text to read as follows:

§ 238.211 Collision posts.

(a) Except as further specified in this paragraph (a), paragraphs (b) through (d) of this section, § 238.201(b), and § 238.209(b)—

* * * * *

■ 18. Revise § 238.213(a)(1) to read as follows:

§ 238.213 Corner posts.

(a)(1) Except as further specified in paragraphs (b) and (c) of this section, § 238.201(b), and § 238.209(b), each passenger car shall have at each end of the car, placed ahead of the occupied volume, two full-height corner posts, each capable of resisting together with its supporting car body structure:

* * * * *

■ 19. Revise the first sentence of § 238.219 to read as follows:

§ 238.219 Truck-to-car-body attachment.

Except as provided in § 238.201(b), passenger equipment shall have a truck-to-carbody attachment with an ultimate strength sufficient to resist without failure the following individually applied loads: 2g vertically on the mass of the truck; and 250,000 pounds in any horizontal direction on the truck, along with the resulting vertical reaction to this load. * * *

Subpart E—Specific Requirements for Tier II Passenger Equipment

■ 20. Revise the first sentence of § 238.401 to read as follows:

§ 238.401 Scope.

This subpart contains specific requirements for railroad passenger equipment operating at speeds exceeding 125 mph but not exceeding 160 mph. * * *

Subpart F—Inspection, Testing, and Maintenance Requirements for Tier II Passenger Equipment

■ 21. Revise § 238.501 to read as follows:

§ 238.501 Scope.

This subpart contains inspection, testing, and maintenance requirements for railroad passenger equipment that operates at speeds exceeding 125 mph but not exceeding 160 mph.

■ 22. Add subpart H to part 238 to read as follows:

Subpart H—Specific Requirements for Tier III Passenger Equipment

Sec.

Subpart H—Specific Requirements for Tier III Passenger Equipment

§ 238.701 Scope.

This subpart contains specific requirements for railroad passenger equipment operating in a shared right-of-way at speeds not exceeding 125 mph and in an exclusive right-of-way without grade crossings at speeds exceeding 125 mph but not exceeding 220 mph. Passenger seating is permitted in the leading unit of a Tier III trainset if the trainset complies with the crashworthiness and occupant protection requirements of this subpart, and the railroad has an approved right-of-way plan under § 213.361 of this chapter and an approved HSR–125 plan under § 236.1007(c) of this chapter. Demonstration of compliance with the requirements of this subpart is subject to FRA review and approval under § 238.111.

§ 238.702 Definitions.

As used in this subpart—

Cab means a compartment or space within a trainset that is designed to be occupied by an engineer and contain an operating console for exercising control over the trainset.

Integrated trainset means a passenger train in which all units of the trainset are designed to operate together to achieve the trainset's structural crashworthiness performance.

Trainset Structure

§ 238.703 Quasi-static compression load requirements.

(a) *General.* To demonstrate resistance to loss of occupied volume, Tier III trainsets shall comply with both the quasi-static compression load requirements in paragraph (b) of this section and the dynamic collision requirements in § 238.705.

(b) *Quasi-static compression load requirements.* (1) Each individual vehicle in a Tier III trainset shall resist a minimum quasi-static end load applied on the collision load path of:

(i) 800,000 pounds without permanent deformation of the occupied volume; or

(ii) 1,000,000 pounds without exceeding either of the following two conditions:

(A) Local plastic strains no greater than 5 percent; and

(B) Vehicle shortening no greater than 1 percent over any 15-foot length of the occupied volume; or

(iii) 1,200,000 pounds without crippling the body structure. Crippling of the body structure is defined as reaching the maximum point on the load-versus-displacement characteristic.

(2) To demonstrate compliance with this section, each type of vehicle shall be subjected to an end compression load (buff) test with an end load magnitude no less than 337,000 lbf (1500 kN).

(3) Compliance with the requirements of paragraph (b) of this section shall be documented and submitted to FRA for review and approval.

§ 238.705 Dynamic collision scenario.

(a) *General.* In addition to the requirements of § 238.703, occupied volume integrity (OVI) shall also be demonstrated for each individual vehicle in a Tier III trainset through an evaluation of a dynamic collision scenario in which a moving train impacts a standing train under the following conditions:

(1) The initially-moving trainset is made up of the equipment undergoing evaluation at its AW0 ready-to-run weight;

(2) If trainsets of varying consist lengths are intended for use in service, then the shortest and longest consist lengths shall be evaluated;

(3) If the initially-moving trainset is intended for use in push-pull service, then, as applicable, each configuration of leading vehicle shall be evaluated separately;

(4) The initially-standing train is led by a rigid locomotive and also made up of five identical passenger coaches having the following characteristics:

(i) The rigid locomotive weighs 260,000 pounds and each coach weighs 95,000 pounds;

(ii) The rigid locomotive and each passenger coach crush in response to applied force as specified in Table 1 to this section; and

(iii) The rigid locomotive shall be modeled using the data inputs listed in appendix H to this part so that it has a geometric design as depicted in Figure 1 to appendix H to this part;

(5) The scenario shall be evaluated on tangent, level track;

(6) The initially-moving trainset shall have an initial velocity of 20 mph if it is an integrated trainset, or an initial velocity of 25 mph if the lead vehicle of the trainset is not part of the integrated design;

(7) The coupler knuckles on the colliding equipment shall be closed and centered;

(8) The initially-moving trainset and initially-standing train consists are not braked;

(9) The initially-standing train has only one degree-of-freedom (longitudinal displacement); and

(10) The model used to demonstrate compliance with the dynamic collision requirements must be validated. Model validation shall be documented and submitted to FRA for review and approval.

(b) *Dynamic collision requirements.* As a result of the impact described in paragraph (a) of this section—

(1) One of the following two conditions must be met for the occupied volume of the initially-moving trainset:

(i) There shall be no more than 10 inches of longitudinal permanent deformation; or

(ii) Global vehicle shortening shall not exceed 1 percent over any 15-foot length of occupied volume.

(2) If Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' Rail Safety and Standards Board Ltd., December 2010, is used to demonstrate compliance with any of the requirements in §§ 238.733, 238.735, 238.737, or 238.743, then the average longitudinal deceleration of the center of gravity (CG) of each vehicle in the initially-moving trainset during the dynamic collision scenario shall not exceed 5g during any 100-millisecond (ms) time period. The maximum interval between data points so averaged in the 100-ms time period shall be no greater than 1-ms.

(3) Compliance with each of the following conditions shall also be demonstrated for the cab of the initially-moving trainset after the impact:

(i) For each seat provided for an employee in the cab, and any floor-

mounted seat in the cab, a survival space shall be maintained where there is no intrusion for a minimum of 12 inches from each edge of the seat. Walls or other items originally within this defined space, not including the operating console, shall not further intrude more than 1.5 inches towards the seat under evaluation;

(ii) There shall be a clear exit path for the occupants of the cab;

(iii) The vertical height of the cab (floor to ceiling) shall not be reduced by more than 20 percent; and

(iv) The operating console shall not have moved more than 2 inches closer to the engineer's seat; if the engineer's seat is part of a set of adjacent seats, the requirements of this paragraph (b)(3) apply to both seats.

TABLE 1—FORCE-VERSUS-CRUSH RELATIONSHIPS FOR PASSENGER COACH AND CONVENTIONAL LOCOMOTIVE

Vehicle	Crush (in)	Force (lbf)
Passenger Coach	0	0
	3	80,000
	6	2,500,000
Conventional Locomotive	0	0
	2.5	100,000
	5	2,500,000

§ 238.707 Override protection.

(a) *Colliding equipment.* (1) Using the dynamic collision scenario described in § 238.705(a), anti-climbing performance shall be evaluated for each of the following sets of initial conditions:

(i) All vehicles in the initially-moving trainset and initially-standing train consists are positioned at their nominal running heights;

(ii) The lead vehicle of the initially-moving trainset shall be perturbed laterally and vertically upwards by 3 inches at the colliding interface; and

(iii) The lead vehicle of the initially-moving trainset shall be perturbed laterally and vertically downwards by 3 inches at the colliding interface.

(2) For each set of initial conditions specified in paragraph (a)(1) of this section, compliance with the following conditions shall be demonstrated after a dynamic impact:

(i) The relative difference in elevation between the underframes of the colliding equipment in the initially-moving trainset and initially-standing train consists shall not change by more than 4 inches; and

(ii) The tread of any wheel of the first vehicle of the initially-moving trainset shall not rise above the top of the rail by more than 4 inches

(b) *Connected equipment override.* (1) Using the dynamic collision scenario described in § 238.705(a), anti-climbing performance shall be evaluated for each of the following sets of initial conditions:

(i) All vehicles in the initially-moving trainset and initially-standing train consists are positioned at their nominal running heights;

(ii) One vehicle is perturbed laterally and vertically upwards by 2 inches, relative to the adjacent vehicle, at the first vehicle-to-vehicle interface in the initially-moving trainset; and,

(iii) One vehicle is perturbed laterally and vertically downwards by 2 inches, relative to the adjacent vehicle, at the first vehicle-to-vehicle interface in the initially-moving trainset.

(2) For each set of initial conditions specified in paragraph (b)(1) of this section, compliance with the following conditions shall be demonstrated after a dynamic impact:

(i) The relative difference in elevation between the underframes of the connected equipment in the initially-moving trainset shall not change by more than 4 inches; and

(ii) The tread of any wheel of the initially-moving trainset shall not rise above the top of rail by more than 4 inches.

§ 238.709 Fluid entry inhibition.

(a) The skin covering the forward-facing end of a Tier III trainset shall be—

(1) Equivalent to a ½-inch steel plate with yield strength of 25,000 pounds per square inch. Material of higher yield strength may be used to decrease the required thickness of the material provided at least an equivalent level of strength is maintained. The sum of the thicknesses of elements (*e.g.,* skin and structural elements) from the structural leading edge of the trainset to a point, when projected onto a vertical plane, just forward of the engineer's normal operating position, may also be used to satisfy this requirement;

(2) Designed to inhibit the entry of fluids into the cab; and

(3) Affixed to the collision posts or other main structural members of the forward end structure so as to add to the strength of the end structure.

(b) Information used to demonstrate compliance with the requirements of this section shall at a minimum include a list and drawings of the structural elements considered in satisfying the thickness-strength requirement of this section, and calculations showing that the thickness-strength requirement is satisfied.

§ 238.711 End structure integrity of cab end.

The cab ends of Tier III trainsets shall comply with the requirements of appendix F to this part to demonstrate the integrity of the end structure. For those units of Tier III trainsets without identifiable corner or collision posts, the requirements of appendix F to this part apply to the end structure at each location specified, regardless of whether the structure is a post.

§ 238.713 End structure integrity of non-cab end.

(a) *General.* Tier III trainsets shall comply with the requirements in paragraphs (b) and (c) of this section to demonstrate the integrity of the end structure for other than the cab ends.

(b) *Collision post requirements.* (1) Each unit of a Tier III trainset shall have at each non-cab end of the unit either:

(i) Two full-height collision posts, located at approximately the one-third points laterally. Each collision post shall have an ultimate longitudinal shear strength of not less than 300,000 pounds at a point even with the top of the underframe member to which it is attached. If reinforcement is used to provide the shear value, the reinforcement shall have full value for a distance of 18 inches up from the underframe connection and then taper to a point approximately 30 inches above the underframe connection; or

(ii) An equivalent end structure that can withstand the sum of forces that each collision post in paragraph (b)(1)(i) of this section is required to withstand. For analysis purposes, the required forces may be assumed to be evenly distributed at the locations where the equivalent structure attaches to the underframe.

(2) Collision posts are not required for the non-cab ends of any unit with push-back couplers and interlocking anti-climbing mechanisms in a Tier III trainset, or the non-cab ends of a semi-permanently coupled consist of trainset units, if the inter-car connection is capable of preventing disengagement and telescoping to the same extent as equipment satisfying the anti-climbing and collision post requirements in subpart C of this part. For demonstrating that the inter-car connection is capable of preventing such disengagement (and telescoping), the criteria in § 238.707(b) apply.

(c) *Corner post requirements.* (1) Each passenger car in a Tier III trainset shall have at each non-cab end of the car, placed ahead of the occupied volume, two side structures capable of resisting a:

(i) 150,000-pound horizontal force applied at floor height without failure;

(ii) 20,000-pound horizontal force applied at roof height without failure; and

(iii) 30,000-pound horizontal force applied at a point 18 inches above the top of the floor without permanent deformation.

(2) For purposes of this paragraph (c), the orientation of the applied horizontal forces shall range from longitudinal inward to transverse inward.

(3) For each evaluation load, the load shall be applied to an area of the structure sufficient to not locally cripple or punch through the material.

(4) The load area shall be chosen to be appropriate for the particular car design and shall not exceed 10 inches by 10 inches.

§ 238.715 Roof and side structure integrity.

To demonstrate roof and side structure integrity, Tier III trainsets shall comply with the requirements in §§ 238.215 and 238.217.

§ 238.717 Truck-to-carbody attachment.

To demonstrate the integrity of truck-to-carbody attachments, each unit in a Tier III trainset shall:

(a) Comply with the requirements in § 238.219; or

(b) Have a truck-to-carbody attachment with strength sufficient to resist, without yielding, the following individually applied, quasi-static loads on the mass of the truck at its CG:

(1) 3g vertically downward;

(2) 1g laterally, along with the resulting vertical reaction to this load; and

(3) Except as provided in paragraph (c) of this section, 5g longitudinally, along with the resulting vertical reaction to this load, provided that for the conditions in the dynamic collision scenario described in § 238.705(a):

(i) The average longitudinal deceleration at the CG of the equipment during the impact does not exceed 5g; and

(ii) The peak longitudinal deceleration of the truck during the impact does not exceed 10g.

(c) As an alternative to demonstrating compliance with paragraph (b)(3) of this section, the truck shall be shown to remain attached after a dynamic impact under the conditions in the collision scenario described in § 238.705(a).

(d) For purposes of paragraph (b) of this section, the mass of the truck includes axles, wheels, bearings, truck-mounted brake system, suspension system components, and any other component attached to the truck by design.

(e) Truck attachment shall be demonstrated using a validated model.

Glazing

§ 238.721 Glazing.

(a) *Cab glazing; end-facing.* (1) Each end-facing exterior window in a cab of a Tier III trainset shall comply with the requirements for Type I glazing in appendix A to part 223 of this chapter, except as provided in paragraphs (a)(2) through (4) of this section.

(2) Instead of the large object impact test specified in appendix A to part 223, each end-facing exterior window in a cab shall demonstrate compliance with the following requirements of this paragraph (a):

(i) The glazing article shall be impacted with a cylindrical projectile that complies with the following design specifications as depicted in Figure 1 to this subpart:

(A) The projectile shall be constructed of aluminum alloy such as ISO 6362–2:1990, grade 2017A, or its demonstrated equivalent;

(B) The projectile end cap shall be made of steel;

(C) The projectile assembly shall weigh 2.2 pounds (−0, +0.044 pounds) or 1 kilogram (kg) (−0, +0.020 kg) and shall have a hemispherical tip. Material may be removed from the interior of the aluminum portion to adjust the projectile mass according to the prescribed tolerance. The hemispherical tip shall have a milled surface with 0.04 inch (1 mm) grooves; and

(D) The projectile shall have an overall diameter of 3.7 inches (94 mm) with a nominal internal diameter of 2.76 inches (70 mm).

(ii) The test of the glazing article shall be deemed satisfactory if the test projectile does not penetrate the windscreen, the windscreen remains in its frame, and the witness plate is not marked by spall.

(iii) A new projectile shall be used for each test.

(iv) The glazing article to be tested shall be that which has the smallest area for each design type. For the test, the glazing article shall be fixed in a frame of the same construction as that mounted on the vehicle.

(v) A minimum of four tests shall be conducted and all must be deemed satisfactory. Two tests shall be conducted with the complete glazing article at 32 °F ± 9 °F (0 °C ± 5 °C) and two tests shall be conducted with the complete glazing article at 68 °F ± 9 °F (20 °C ± 5 °C). For the tests to be valid they shall demonstrate that the core temperature of the complete glazing article during each test is within the required temperature range.

(vi) The test glazing article shall be mounted at the same angle relative to the projectile path as it will be to the direction of travel when mounted on the vehicle.

(vii) The projectile's impact velocity shall equal the maximum operating speed of the Tier III trainset plus 100 mph (160 km/h). The projectile velocity shall be measured within 13 feet (4 m) of the point of impact.

(viii) The point of impact shall be at the geometrical center of the glazing article.

(3) Representative samples for large object impact testing of large Tier III end-facing cab glazing articles may be used instead of the actual design size, provided that the following conditions are met:

(i) Testing of glazing articles having dimensions greater than 39.4 by 27.6 inches (1,000 mm by 700 mm), excluding framing, may be performed using a flat sample having the same composition as the glazing article for which compliance is to be demonstrated. The glazing manufacturer shall provide documentation containing its technical justification that testing a flat sample is sufficient to verify compliance of the glazing article with the requirements of this paragraph (a).

(ii) Flat sample testing is permitted only when no surface of the full-size glazing article contains curvature with a radius less than 98 inches (2,500 mm), and when a complete, finished glazing article is laid (convex side uppermost) on a flat horizontal surface, the distance (measured perpendicularly to the flat surface) between the flat surface and the inside face of the glazing article is not greater than 8 inches (200 mm).

(4) End-facing glazing shall demonstrate sufficient resistance to spalling, as verified by the large impact projectile test under the following conditions:

(i) An annealed aluminum witness plate of maximum thickness 0.006 inch (0.15 mm) and of dimension 19.7 by 19.7 inches (500 mm by 500 mm) is placed vertically behind the sample under test, at a horizontal distance of 500 mm from the point of impact in the direction of travel of the projectile or the distance between the point of impact of the projectile and the location of the engineer's eyes in the engineer's normal operating position, whichever is less. The center of the witness plate is aligned with the point of impact.

(ii) Spalling performance shall be deemed satisfactory if the aluminum witness plate is not marked.

(iii) For the purposes of this subpart, materials used specifically to protect the cab occupants from spall (*i.e.,* spall

shields) shall not be required to meet the flammability and smoke emission performance requirements of appendix B to this part.

(5) Each end-facing exterior window in a cab shall, at a minimum, provide ballistic penetration resistance that meets the requirements of appendix A to part 223.

(6) Each end-facing exterior window in a cab shall be permanently marked, before installation, in such a manner that the marking is clearly visible after the material has been installed. The marking shall include:

(i) The words ''FRA TYPE IHS'' to indicate that the material has successfully passed the testing requirements specified in this paragraph (a);

(ii) The name of the manufacturer; and

(iii) The type or brand identification of the material.

(b) *Cab glazing; side-facing.* Each side-facing exterior window in a cab of a Tier III trainset shall—

(1) Comply with the requirements for Type II glazing contained in appendix A to part 223 of this chapter, for large-object impact; and

(2) Maintain the minimum ballistics penetration resistance as required for end-facing glazing in paragraph (a)(5) of this section.

(c) *Non-cab glazing; side-facing.* (1) Except as provided in paragraph (c)(2) of this section, each side-facing exterior window in other than a cab shall comply with the requirements for Type II glazing contained in appendix A to part 223 of this chapter.

(2) Instead of the requirements specified in paragraph (c)(1) of this section, a side-facing exterior window intended to be breakable and serve as an emergency window exit may comply with an alternative standard that provides an equivalent level of safety and is approved for use by FRA.

(d) *Glazing securement.* Each exterior window shall remain in place when subjected to:

(1) The forces due to air pressure differences caused when two trains pass at the minimum separation for two adjacent tracks, while traveling in opposite directions, each train traveling at the maximum authorized speed; and

(2) The impact forces that the exterior window is required to resist as specified in this section.

(e) *Glazing certification.* (1) Each manufacturer that provides glazing materials, intended by the manufacturer for use in achieving compliance with the requirements of this section, shall certify that each type of glazing material being supplied for this purpose has been successfully tested. Tests performed on glazing materials for demonstration of compliance with this section, relied on by the glazing manufacturer in furtherance of certification, may be performed by either:

(i) An independent third-party (laboratory, facility, underwriter); or

(ii) The glazing manufacturer, by providing FRA the opportunity to witness all tests by written notice at least 30 days prior to testing.

(2) Any glazing material certified to meet the requirements of this section shall be re-certified by the same means (as originally certified) if any changes are made to the glazing that may affect its mechanical properties or its mounting arrangement on the vehicle.

(3) All certification/re-certification documentation shall be made available to FRA upon request.

Brake System

§ 238.731 Brake system.

(a) *General.* Each railroad shall demonstrate through analysis and testing the maximum safe operating speed for its Tier III trainsets that results in no thermal damage to equipment or infrastructure during normal operation of the brake system.

(b) *Minimum performance requirement for brake system.* Each Tier III trainset's brake system shall be capable of stopping the trainset from its maximum operating speed within the signal spacing existing on the track over which the trainset is operating under the worst-case adhesion conditions defined by the railroad, as approved by FRA.

(c) *Emergency brake system.* A Tier III trainset shall be provided with an emergency brake application feature that produces an irretrievable stop. An emergency brake application shall be available at any time, and shall be initiated by either of the following:

(1) An unintentional parting of the trainset; or

(2) The train crew at locations within the trainset specified by the railroad, as approved by FRA.

(d) *Passenger brake alarm.* (1) A means to initiate a passenger brake alarm shall be provided at two locations in each unit of a Tier III trainset that is over 45 feet in length. When a unit of the trainset is 45 feet or less in length, a means to initiate a passenger brake alarm need only be provided at one location in the unit. These locations shall be identified by the railroad as approved by FRA. The words ''Passenger Brake Alarm'' shall be legibly stenciled or marked on each device or on an adjacent badge plate.

(2) All passenger brake alarms shall be installed so as to prevent accidental activation.

(3) During departure from the boarding platform, activation of the passenger brake alarm shall result in an emergency brake application.

(4) A passenger brake alarm activation that occurs after the trainset has safely cleared the boarding platform shall be acknowledged by the engineer within the time period specified by the railroad, as approved by FRA, for train operation to remain under the full control of the engineer. The method used to confirm that the trainset has safely cleared the boarding platform shall be defined by the railroad as approved by FRA.

(5) If the engineer does not acknowledge the passenger brake alarm as specified in paragraph (d)(4) of this section, at a minimum, a retrievable full service brake application shall be automatically initiated until the trainset has stopped unless the engineer intervenes as described in paragraph (d)(6) of this section.

(6) To retrieve the full service brake application described in paragraph (d)(5) of this section, the engineer must acknowledge the passenger brake alarm and activate appropriate controls to issue a command for brake application as specified by the railroad, as approved by FRA.

(e) *Degraded performance of blended brake system.* The following requirements of this paragraph (e) apply to operation of Tier III trainsets with blended braking systems, to address degraded brake system performance:

(1) Loss of power or failure of the dynamic or regenerative brake shall not result in exceeding the allowable stopping distance defined by the railroad as approved by FRA;

(2) The available friction braking shall be adequate to stop the trainset safely under the operating conditions defined by the railroad, as approved by FRA;

(3) The operational status of the trainset brake system shall be displayed for the engineer in the operating cab; and

(4) The railroad shall demonstrate through analysis and testing the maximum speed for safely operating its Tier III trainsets using only the friction brake portion of the blended brake with no thermal damage to equipment or infrastructure. The analysis and testing shall also be used to determine the maximum safe operating speed for various percentages of operative friction brakes and shall be included in the railroad's ITM program.

(f) *Main reservoir system.* (1) The main reservoirs in a Tier III trainset

shall be designed and tested to meet the requirements of a recognized standard specified by the railroad as approved by FRA, such as the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code for Unfired Pressure Vessel Section VIII, Division I (ASME Code). The working pressure shall be 150 psig (10.3 bar) and the corresponding rated temperature shall be 150 °F (65 °C) unless otherwise defined by the railroad as approved by FRA. Reservoirs shall be certified based on their size and volume requirements.

(2) Each welded steel main reservoir shall be drilled in accordance with the requirements of a recognized standard specified by the railroad as approved by FRA, such as paragraph UG–25(e) of Section VIII of the ASME Boiler and Pressure Vessel Code. With the drain opening located at the low point of the reservoir, one row of holes shall be drilled lengthwise on the reservoir on a line intersecting the drain opening and sloped to the drain opening.

(3) A breach of a welded steel main reservoir at any of the drilled holes described in paragraph (f)(2) of this section shall be cause for the reservoir to be condemned and withdrawn from service. Any type of welded repair to a steel main reservoir is prohibited.

(g) *Aluminum main reservoirs.* (1) Aluminum main reservoirs used in a Tier III trainset shall conform to the requirements of § 229.51 of this chapter.

(2) Any type of welded repair to an aluminum main reservoir is prohibited.

(h) *Main reservoir tests.* Prior to initial installation, each main reservoir shall be subjected to a pneumatic or hydrostatic pressure test based on the maximum working pressure defined in paragraph (f) or (g) of this section, as appropriate, unless otherwise established by the railroad's ITM program. Records of the test date, location, and pressure shall be maintained by the railroad for the life of the equipment. Periodic inspection requirements for main reservoirs shall be defined in the railroad's ITM program.

(i) *Brake gauges.* All mechanical gauges and all devices providing electronic indication of air pressure that are used by the engineer to aid in the control or braking of a Tier III trainset shall be located so they may be conveniently read from the engineer's normal position during operation of the trainset.

(j) *Brake application/release.* (1) Brake actuators shall be designed to provide brake pad and shoe clearance when the brakes are released.

(2) The minimum brake cylinder pressure shall be established by the railroad, as approved by FRA, to provide adequate adjustment from minimum service to full service for proper train operation.

(k) *Foundation brake gear.* The railroad shall specify requirements in its ITM program for the inspection, testing, and maintenance of the foundation brake gear.

(l) *Leakage.* (1) If a Tier III trainset is equipped with a brake pipe, the leakage rates shall not exceed the limits defined in either paragraph (l)(2) of this section, or those defined in the Air Consumption Analysis included in the railroad ITM program, whichever is more restrictive. The method of inspection for main reservoir pipe leakage shall be prescribed in the railroad's ITM program.

(2) Brake pipe leakage may not exceed 5 p.s.i. per minute; and with a full service application at maximum brake pipe pressure and with communication to the brake cylinders closed, the brakes shall remain applied for at least 5 minutes.

(m) *Slide protection and alarm.* (1) A Tier III trainset shall be equipped with an adhesion control system designed to automatically adjust the braking force on each wheel to prevent sliding during braking.

(2) A wheel-slide alarm that is visual or audible, or both, shall alert the engineer in the operating cab to wheel-slide conditions on any axle of the trainset.

(3) The railroad shall specify operating restrictions for trainsets with slide protection devices for when they fail to prevent wheel slide within safety parameters preset by the railroad. Both the operating restrictions and safety parameters shall be approved by FRA.

(n) *Monitoring and diagnostics.* Each Tier III trainset shall be equipped with a monitoring and diagnostic system that is designed to automatically assess the functionality of the brake system for the entire trainset. Details of the system operation and the method of communication of brake system functionality prior to the departure of the trainset and while en route shall be described in detail in the railroad's ITM program.

(o) *Train securement.* Independent of the pneumatic brakes, Tier III equipment shall be equipped with a means of securing the equipment against unintentional movement when left standing and unmanned in such a manner that the brake system of the equipment cannot be readily controlled by a qualified person. The railroad shall develop the procedures used to secure the equipment and shall also demonstrate that those procedures effectively secure the equipment on all grade conditions identified by the railroad, as approved by FRA.

(p) *Rescue operation; brake system.* A Tier III trainset's brake system shall be designed to allow a rescue vehicle or trainset to control its brakes when the trainset is disabled.

Interior Fittings and Surfaces

§ 238.733 Interior fixture attachment.

(a) Tier III trainsets shall comply with the interior fixture attachment strength requirements referenced in either of the following paragraphs:

(1) Section 238.233 and APTA PR–CS–S–006–98; or

(2) Section 6.1.4, ''Security of furniture, equipment and features,'' of GM/RT2100, provided that—

(i) The conditions of § 238.705(b)(2) are met;

(ii) Interior fixture attachment strength is sufficient to resist without failure individually applied loads of 5g longitudinal, 3g lateral, and 3g vertical when applied to the mass of the fixture; and

(iii) Use of the standard is carried out under any conditions identified by the railroad, as approved by FRA.

(b) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) American Public Transportation Association, 1666 K Street NW, Washington, DC 20006, *www.aptastandards.com.*

(i) APTA PR–CS–S–006–98, Rev. 1, ''Standard for Attachment Strength of Interior Fittings for Passenger Railroad Equipment,'' Authorized September 28, 2005.

(ii) [Reserved]

(2) Rail Safety and Standards Board Ltd., Communications, RSSB, Block 2 Angel Square, 1 Torrens Street, London, England EC1V 1NY, *www.rgsonline.co.uk.*

(i) Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' December 2010.

(ii) [Reserved]

§ 238.735 Seat crashworthiness (passenger and cab crew).

(a) Passenger seating in Tier III trainsets shall comply with the requirements referenced in either of the following paragraphs:

(1) Section 238.233 and APTA PR–CS–S–016–99 excluding Section 6, ''Seat durability testing;'' or

(2) Section 6.2, ''Seats for passengers, personnel, or train crew,'' of GM/RT2100, provided that—

(i) The conditions of § 238.705(b)(2) are met;

(ii) Seat attachment strength is sufficient to resist without failure individually applied loads of 5g longitudinal, 3g lateral, and 3g applied to the mass of the seat; and

(iii) Use of the standard is carried out under any conditions identified by the railroad, as approved by FRA.

(b) Each seat provided for an employee in the cab of a Tier III trainset, and any floor-mounted seat in the cab, shall comply with § 238.233(e), (f), and (g).

(c) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and are available from the sources indicated below. They are also available for inspection at NARA. For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(1) American Public Transportation Association, 1666 K Street NW, Washington, DC 20006, *www.aptastandards.com*.

(i) APTA PR–CS–S–016–99, Rev. 2, ''Standard for Passenger Seats in Passenger Rail Cars,'' Authorized October 3, 2010.

(ii) [Reserved]

(2) Rail Safety and Standards Board Ltd., Communications, RSSB, Block 2 Angel Square, 1 Torrens Street, London, England EC1V 1NY, *www.rgsonline.co.uk*.

(i) Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' December 2010.

(ii) [Reserved]

§ 238.737 Luggage racks.

(a) Overhead storage racks shall provide longitudinal and lateral restraint for stowed articles. These racks shall incorporate transverse dividers at a maximum spacing of 10 ft. (3 m) to restrain the longitudinal movement of luggage. To restrain the lateral movement of luggage, these racks shall also slope downward in the outboard direction at a minimum ratio of 1:8 with respect to a horizontal plane.

(b) Luggage racks shall comply with the requirements in either of the following paragraphs:

(1) Section 238.233; or

(2) Section 6.8, ''Luggage stowage,'' of GM/RT2100, provided that—

(i) The conditions of § 238.705(b)(2) are met;

(ii) Attachment strength is sufficient to resist without failure individually applied loads of 5g longitudinal, 3g lateral, and 3g vertical; and

(iii) Use of the standard is carried out under any conditions identified by the railroad, as approved by FRA. In particular, the railroad shall determine the maximum allowable weight of the luggage stowed for purposes of evaluating luggage rack attachment strength.

(c) Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' December 2010 is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and is available from Rail Safety and Standards Board Ltd., Communications, RSSB, Block 2 Angel Square, 1 Torrens Street, London, England EC1V 1NY, *www.rgsonline.co.uk*. It is also available for inspection at NARA. For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Emergency Systems

§ 238.741 Emergency window egress and rescue access.

(a) *Emergency window egress and rescue access plan.* If a passenger car in a Tier III trainset is not designed to comply with the requirements in § 238.113 or § 238.114, the railroad shall submit to FRA for approval an emergency window egress and rescue access plan during the design review stage. The plan must include, but is not limited to, the elements in this section.

(b) *Ease of operability.* If an emergency window exit in a passenger car requires the use of a tool, other implement (*e.g.,* hammer), or a mechanism to permit removal of the window panel from the inside of the car during an emergency situation, then the plan must demonstrate the use of the device provides a level of safety equivalent to that required by § 238.113(b). In particular, the plan must address the location, design, and signage and instructions for the device. The railroad shall also include a provision in its Tier III ITM program to inspect for the presence of the device at least each day the car is in service.

(c) *Dimensions.* If the dimensions of a window opening in a passenger car do not comply with the requirements in § 238.113 or § 238.114, then the plan must demonstrate that at least an equivalent level of safety is provided.

(d) *Alternative emergency evacuation openings.* If a passenger car employs the use of emergency egress panels or additional door exits instead of emergency window exits or rescue access windows, then the plan must demonstrate that such alternative emergency evacuation openings provide a level of safety at least equivalent to that required by § 238.113 or § 238.114, or both as appropriate. The plan must address the location, design, and signage and instructions for the alternative emergency evacuation openings.

§ 238.743 Emergency lighting.

(a) Except as provided in paragraph (b) of this section, Tier III trainsets shall comply with the emergency lighting requirements specified in § 238.115.

(b) Emergency lighting back-up power systems shall, at a minimum, be capable of operating after experiencing the individually applied accelerations defined in either of the following paragraphs:

(1) Section 238.115(a)(4)(ii); or

(2) Section 6.1.4, ''Security of furniture, equipment and features,'' of GM/RT2100, provided that—

(i) The conditions of § 238.705(b)(2) are met;

(ii) The initial shock of a collision or derailment is based on a minimum load of 5g longitudinal, 3g lateral, and 3g vertical; and

(iii) Use of the standard is carried out under any conditions identified by the railroad, as approved by FRA.

(c) Railway Group Standard GM/RT2100, Issue Four, ''Requirements for Rail Vehicle Structures,'' December 2010, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and is available from Rail Safety and Standards Board Ltd., Communications,

RSSB, Block 2 Angel Square, 1 Torrens Street, London, England EC1V 1NY, *www.rgsonline.co.uk*. It is also available for inspection at NARA. For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Cab Equipment

§ 238.751 Alerters.

(a) An alerter shall be provided in the operating cab of each Tier III trainset, unless in accordance with paragraph (e) of this section the trainset operates in a territory where an alternate technology providing equivalent safety is installed, such as redundant automatic train control or redundant automatic train stop system.

(b) Upon initiation of the alerter, the engineer must acknowledge the alerter within the time period and according to the parameters specified by the railroad, as approved by FRA, in order for train operations to remain under the full control of the engineer.

(c) If the engineer does not acknowledge the alerter as specified in paragraph (b) of this section, at a minimum a retrievable full service brake application shall occur until the train has stopped, unless the crew intervenes as described in paragraph (d) of this section.

(d) To retrieve the full service brake application described in paragraph (c) of this section, the engineer must acknowledge the alerter and activate appropriate controls to issue a command for brake application as specified by the railroad and approved by FRA.

(e) If an alternate technology to the alerter is used, the railroad shall conduct an analysis that confirms the ability of the technology to provide an equivalent level of safety. This analysis shall be approved by FRA.

§ 238.753 Sanders.

(a) A Tier III trainset shall be equipped with operative sanders, if required by the railroad and as approved by FRA.

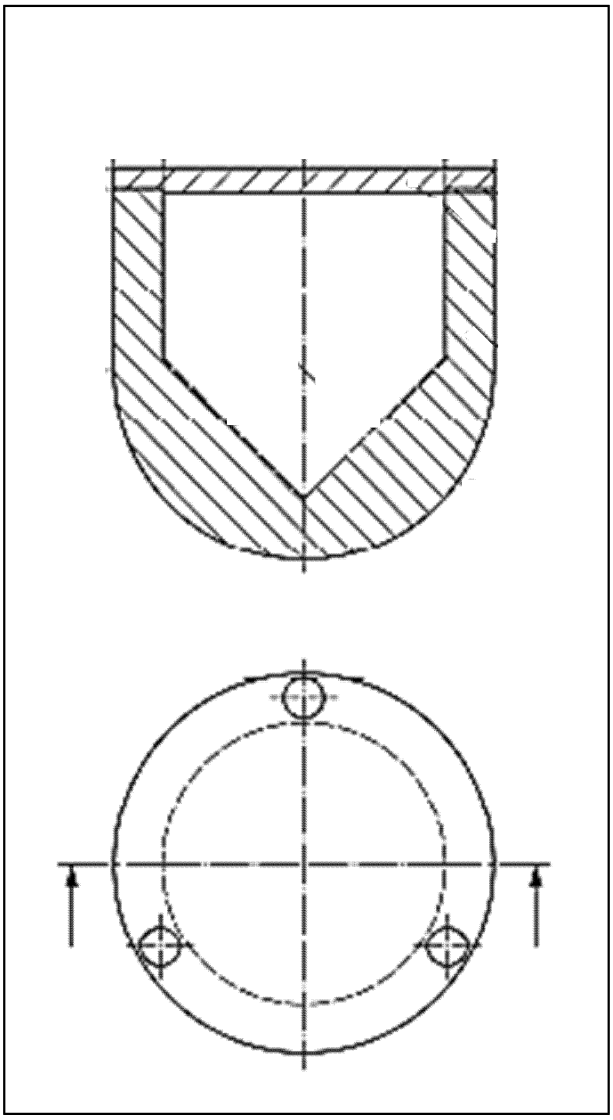
(b) Sanders required under this section shall comply with § 229.131(a), (b), and (d) of this chapter, except that instead of the requirements of §§ 229.9 and 229.23 of this chapter:

(1) The requirements of § 238.17 shall apply to the tagging and movement of a Tier III trainset with defective sanders; and

(2) The requirements of the railroad's ITM program shall apply to the next periodic inspection of such a trainset.

(c) In addition to the requirements in paragraph (b) of this section, the railroad's ITM program shall specify the inspection, testing, and maintenance requirements for Tier III trainsets equipped with sanders.

Figure 1 to Subpart H of Part 238—Cylindrical Projectile for Use in § 238.721 End-Facing Cab-Glazing Testing



■ 23. Add and reserve subpart I to part 238 to read as follows:

Subpart I—Inspection, Testing, and Maintenance Requirements for Tier III Passenger Equipment—[Reserved]

■ 24. Appendix A to part 238 is amended by adding, in alphabetical order, the entry for new subpart H to read as follows:

APPENDIX A TO PART 238—SCHEDULE OF CIVIL PENALTIES [1] [2]

Section		Violation	Willful violation
*	* * * * * * *		
SUBPART H—SPECIFIC REQUIREMENTS FOR TIER III PASSENGER EQUIPMENT			
238.703	Quasi-static compression load requirements	2,500	5,000
238.705	Dynamic collision scenario	2,500	5,000
238.707	Override protection	2,500	5,000

APPENDIX A TO PART 238—SCHEDULE OF CIVIL PENALTIES [1] [2]—Continued

Section		Violation	Willful violation
238.709	Fluid entry inhibition	2,500	5,000
238.711	End structure integrity of cab end	2,500	5,000
238.713	End structure integrity of non-cab end	2,500	5,000
238.715	Roof and side structure integrity	2,500	5,000
238.717	Truck-to-car-body attachment	2,500	5,000
238.721	Glazing	2,500	5,000
238.731	Brake system	2,500	5,000
238.733	Interior fixture attachment	2,500	5,000
238.735	Seat crashworthiness	2,500	5,000
238.737	Luggage racks	2,500	5,000
238.741	Emergency window egress and rescue access	2,500	5,000
238.751	Alerters	2,500	5,000
238.753	Sanders	1,000	2,000

[1] A penalty may be assessed against an individual only for a willful violation. Generally, when two or more violations of these regulations are discovered with respect to a single unit of passenger equipment that is placed or continued in service by a railroad, the appropriate penalties set forth above are aggregated up to a maximum of $27,904 per day. However, failure to perform, with respect to a particular unit of passenger equipment, any of the inspections and tests required under subparts D and F of this part will be treated as a violation separate and distinct from, and in addition to, any substantive violative conditions found on that unit of passenger equipment. Moreover, the Administrator reserves the right to assess a penalty of up to the statutory maximum amount for any violation where circumstances warrant. See 49 CFR part 209, appendix A.

Failure to observe any condition for movement of defective equipment set forth in § 238.17 will deprive the railroad of the benefit of the movement-for-repair provision and make the railroad and any responsible individuals liable for penalty under the particular regulatory section(s) concerning the substantive defect(s) present on the unit of passenger equipment at the time of movement.

Failure to observe any condition for the movement of passenger equipment containing defective safety appliances, other than power brakes, set forth in § 238.17(e) will deprive the railroad of the movement-for-repair provision and make the railroad and any responsible individuals liable for penalty under the particular regulatory section(s) contained in part 231 of this chapter or § 238.429 concerning the substantive defective condition.

The penalties listed for failure to perform the exterior and interior mechanical inspections and tests required under § 238.303 and § 238.305 may be assessed for each unit of passenger equipment contained in a train that is not properly inspected. Whereas, the penalties listed for failure to perform the brake inspections and tests under § 238.313 through § 238.319 may be assessed for each train that is not properly inspected.

[2] The penalty schedule uses section numbers from 49 CFR part 238. If more than one item is listed as a type of violation of a given section, each item is also designated by a ''penalty code,'' which is used to facilitate assessment of civil penalties, and which may or may not correspond to any subsection designation(s). For convenience, penalty citations will cite the CFR section and the penalty code, if any. FRA reserves the right, should litigation become necessary, to substitute in its complaint the CFR citation in place of the combined CFR and penalty code citation, should they differ.

■ 25. Amend paragraph (c) of Appendix B to part 238 by adding two sentences to the end of note 16 of the table of ''Test Procedures and Performance Criteria for the Flammability and Smoke Emission Characteristics of Materials Used in Passenger Cars and Locomotive Cabs'' to read as follows:

Appendix B to Part 238—Test Methods and Performance Criteria for the Flammability and Smoke Emission Characteristics of Materials Used in Passenger Cars and Locomotive Cabs

* * * * *

(c) * * *

16 * * * For purposes of this Note, the floor assembly of a vehicle in a Tier III trainset may be tested together with undercar design features that separate the vehicle from the fire source, *i.e.,* skirts and bottom covers, to protect against a fire source under and external to the vehicle. To assess the safety associated with testing the floor assembly in this manner, and to protect against a fire source under the floor assembly but internal to the vehicle, safety must also be demonstrated by conducting a fire hazard analysis that includes the considerations in Note 17.

* * * * *

■ 26. Amend the introductory text of appendix F to part 238 by adding a third paragraph to read as follows:

Appendix F to Part 238—Alternative Dynamic Performance Requirements for Front End Structures of Cab Cars and MU Locomotives

* * * * *

Although the requirements of this appendix are stated in terms applicable to Tier I passenger equipment, they are also applicable to Tier III passenger trainsets under § 238.711. Specifically, the cab ends of Tier III trainsets shall comply with the requirements of this appendix to demonstrate the integrity of the end structure.

* * * * *

■ 27. Add appendix G to part 238 to read as follows:

Appendix G to Part 238—Alternative Requirements for Evaluating the Crashworthiness and Occupant Protection Performance of Tier I Passenger Trainsets

General

This appendix applies to Tier I alternative passenger trainsets, as described below. While the appendix may refer to specific units of rail equipment in a trainset, the alternative requirements in this appendix apply only to a trainset as a whole.

This appendix specifies alternatives to the crashworthiness and occupant protection performance requirements for Tier I passenger equipment in §§ 238.203, Static end strength; 238.205, Anti-climbing mechanism; 238.207, Link between coupling mechanism and car body; 238.209(a), Forward end structure of locomotives, including cab cars and MU locomotives; 238.211, Collision posts; 238.213, Corner posts; and 238.219, Truck-to-carbody attachment. To maintain their integrity, these requirements apply as a whole. They also apply in addition to the requirements of §§ 238.209(b); 238.215, Rollover strength; 238.217, Side structure; and 238.233, Interior fittings and surfaces; and they apply with APTA standards for occupant protection, as specified in this appendix.

For ease of comparison with the Tier I requirements in subpart C of this part, this appendix is arranged in order by the Tier I section referenced.

Use of this appendix to demonstrate alternative crashworthiness and occupant protection performance for Tier I passenger equipment is subject to FRA review and approval under § 238.201.

Occupied Volume Integrity

(a) Instead of the requirements of § 238.203, the units of a Tier I alternative passenger trainset may demonstrate their occupied volume integrity by complying with both the quasi-static compression load and dynamic collision requirements in §§ 238.703(b) and 238.705, respectively.

Override Protection

(b) *Colliding equipment.* Instead of the requirements of § 238.205, the units of a Tier I alternative passenger trainset may

demonstrate their ability to resist vertical climbing and override at each colliding interface during a train-to-train collision by complying with the dynamic collision requirements in § 238.707(a).

(c) *Connected equipment.* Instead of the requirements of §§ 238.205 and 238.207, when connected, the units of a Tier I alternative passenger trainset may demonstrate their ability to resist vertical climbing and override by complying with the dynamic collision requirements in § 238.707(b).

Fluid Entry Inhibition

(d) Instead of the requirements of § 238.209(a), each cab end of a Tier I alternative passenger trainset may demonstrate its ability to inhibit fluid entry and provide other penetration resistance by complying with the requirements in § 238.709.

End Structure Integrity of Cab End

(e) Each cab end of a Tier I alternative passenger trainset is subject to the requirements of appendix F to this part to demonstrate cab end structure integrity. For those cab ends without identifiable corner or collision posts, the requirements of appendix F to this part apply to the end structure at the specified locations, regardless of whether the structure at the specified locations is a post.

End Structure Integrity of Non–Cab End

(f) Instead of the applicable requirements of §§ 238.211 and 238.213, the units of a Tier I alternative trainset may demonstrate end structure integrity for other than a cab end by complying with the requirements in § 238.713(b) and (c).

Roof and Side Structure Integrity

(g) A Tier I alternative passenger trainset is subject to the requirements of §§ 238.215 and 238.217 to demonstrate roof and side structure integrity.

Truck Attachment

(h) Instead of the requirements of § 238.219, the units of a Tier I alternative passenger trainset may demonstrate their truck-to-carbody attachment integrity by complying with the requirements in § 238.717 (b) through (e).

Interior Fixture Attachment

(i)(1) A Tier I alternative passenger trainset is subject to the interior fixture requirements in § 238.233. Interior fixtures must also comply with APTA PR–CS–S–006–98, Rev. 1, ''Standard for Attachment Strength of Interior Fittings for Passenger Railroad Equipment,'' Authorized September 28, 2005, and those portions of APTA PR–CS–S–034–99, Rev. 2, ''Standard for the Design and Construction of Passenger Railroad Rolling Stock,'' Authorized June 11, 2006, relating to interior fixtures.

(2) The standards required in this paragraph (i) are incorporated by reference into this paragraph with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and available from the American Public Transportation Association, 1666 K Street NW, Washington, DC 20006, *www.aptastandards.com*. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(i) APTA PR–CS–S–006–98, Rev. 1, ''Standard for Attachment Strength of Interior Fittings for Passenger Railroad Equipment,'' Authorized September 28, 2005.

(ii) APTA PR–CS–S–034–99, Rev. 2, ''Standard for the Design and Construction of Passenger Railroad Rolling Stock,'' Authorized June 11, 2006.

Seat Crashworthiness (Passenger and Crew)

(j) *Passenger seating.* (1) Passenger seating in a Tier I alternative passenger trainset is subject to the requirements for seats in § 238.233 and must also comply with APTA PR–CS–S–016–99, Rev. 2, ''Standard for Passenger Seats in Passenger Rail Cars,'' Authorized October 3, 2010, with the exception of Section 6, ''Seat durability testing.''

(2) APTA PR–CS–S–016–99, Rev. 2, ''Standard for Passenger Seats in Passenger Rail Cars,'' Authorized October 3, 2010, is incorporated by reference into this paragraph (j) with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at Federal Railroad Administration, Docket Clerk, 1200 New Jersey Avenue SE, Washington, DC and is available from the American Public Transportation Association, 1666 K Street NW, Washington, DC 20006, *www.aptastandards.com*. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *www.archives.gov/federal-register/cfr/ibr-locations.html*.

(k) *Crew seating.* Each seat provided for an employee regularly assigned to occupy the cab of a Tier I alternative passenger trainset, and any floor-mounted seat in the cab, must comply with § 238.233(e), (f), and (g).

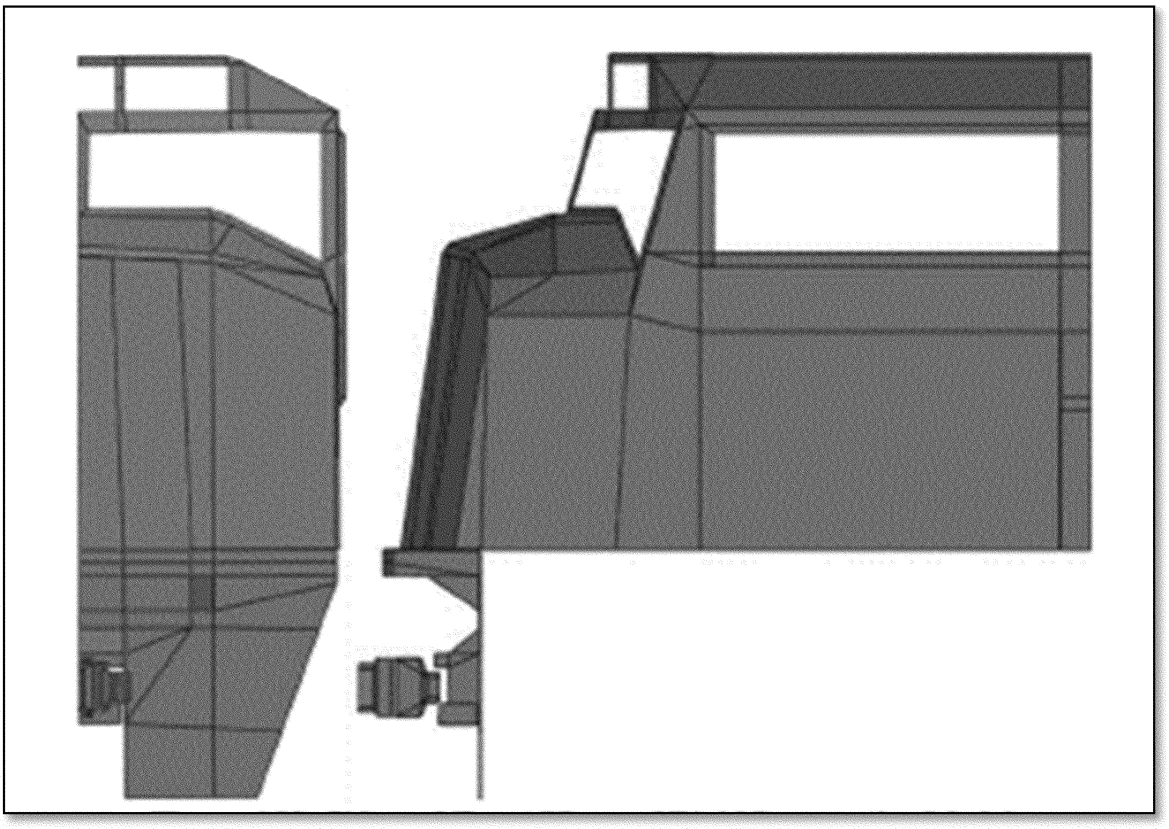
■ 28. Add appendix H to part 238 to read as follows:

Appendix H to Part 238—Rigid Locomotive Design Computer Model Input Data and Geometrical Depiction

(a) As specified in § 238.705(a)(4), this appendix provides input data and a geometrical depiction necessary to create a computer model of the rigid locomotive design for use in evaluating the occupied volume integrity of a Tier III trainset in a dynamic collision scenario. (This appendix may also be applied to a Tier I alternative passenger trainset to evaluate its occupied volume integrity, in accordance with appendix G to this part).

(b) The input data, in the form of an input file, contains the geometry for approximately the first 12 feet of the rigid locomotive design. Because this input file is for a half-symmetric model, a locomotive mass corresponding to 130,000 pounds of weight is provided for modeling purposes—half the 260,000 pounds of weight specified for the locomotive in § 238.705(a)(4). Figure 1 to this appendix provides two views of the locomotive's geometric depiction. The input data is contained in Appendix C to FRA's Technical Criteria and Procedures Report, available at *http://www.fra.dot.gov/eLib/details/L01292#p4_z50_gD_lRT*.

Figure 1 to Appendix H—Side and Front Views of Rigid Locomotive Model



Issued in Washington, DC.

Ronald L. Batory,

Administrator.

[FR Doc. 2018–25020 Filed 11–20–18; 8:45 am]

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Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Candy Darter; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2018–0050; 4500090023]

RIN 1018–BD15

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Candy Darter

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the candy darter (*Etheostoma osburni*) under the Endangered Species Act (Act). In total, approximately 596 stream kilometers (370 stream miles), in Virginia and West Virginia, fall within the boundaries of the proposed critical habitat designation. If we finalize this rule as proposed, it would extend the Act's protections to this species' critical habitat. We also announce the availability of a draft economic analysis (DEA) of the proposed designation of critical habitat for the candy darter. Elsewhere in the **Federal Register** today, we published a final rule listing the candy darter as an endangered species under the Act.

DATES: We will accept comments on the proposed rule or DEA that are received or postmarked on or before January 22, 2019. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by January 7, 2019.

ADDRESSES: You may submit comments on the proposed rule or DEA by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov*. In the Search box, enter FWS–R5–ES–2018–0050, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: Docket No. FWS–R5–ES–2018–0050, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see *Public Comments,* below, for more information).

Document availability: The DEA is available at *https://www.fws.gov/northeast/candydarter,* at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2018–0050, at the West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**), and at the Southwestern Virginia Ecological Services Field Office (330 Cummings Street, Abingdon, VA 24210–3208).

The coordinates or plot points or both from which the maps are generated are included in the administrative record for this critical habitat designation and are available at *https://www.fws.gov/northeast/candydarter,* at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2018–0050, and at the West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**) or Southwestern Virginia Ecological Services Field Office (address provided above). Any additional tools or supporting information that we may develop for this critical habitat designation will also be available at the Fish and Wildlife Service website and Field Offices set out above, and may also be included in the preamble and/or at *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John Schmidt, Field Supervisor, U.S. Fish and Wildlife Service, West Virginia Ecological Services Field Office, 694 Beverly Pike, Elkins, WV 26241–9475; telephone 304–636–6586. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act, any species that is determined to be endangered or threatened requires critical habitat to be designated, to the maximum extent prudent and determinable. Designations and revisions of critical habitat can be completed only by issuing a rule.

This rule proposes to designate critical habitat for the candy darter (*Etheostoma osburni*). Elsewhere in today's **Federal Register**, we published a rule to list the candy darter as an endangered species under the Act.

The basis for our action. Under the Endangered Species Act, any species that is determined to be an endangered or a threatened species shall, to the maximum extent prudent and determinable, have habitat designated that is considered to be critical habitat. Section 4(b)(2) of the Endangered Species Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, the impact on national security, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species.

We prepared an economic analysis of the proposed designation of critical habitat. To consider economic impacts, we prepared an analysis of the economic impacts of the proposed critical habitat designation. We hereby announce the availability of the draft economic analysis and seek public review and comment.

In the near future. We intend to reestablish populations within the candy darter's historical range under section 10(j) of the Act in a future publication, and we are seeking public input on other potential recovery tools and on areas currently unoccupied by the candy darter within the historical range that contain essential physical and biological features (see Exclusions, below, for more detail).

Information Requested

Public Comments

We intend that any final action resulting from this proposed rule will be based on the best scientific data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned government agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*) including whether there are threats to the species from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of

designation such that the designation of critical habitat may not be prudent.

(2) Specific information on:

(a) The amount and distribution of candy darter habitat;

(b) What areas, that were occupied at the time of listing and that contain the physical or biological features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change; and

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why.

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(4) Information on the projected and reasonably likely impacts of climate change on the candy darter and proposed critical habitat.

(5) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the benefits of including or excluding areas that may be impacted.

(6) Information on the extent to which the description of probable economic impacts in the draft economic analysis (DEA) is a reasonable estimate of the likely economic impacts.

(7) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(8) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

(9) Information about currently unoccupied areas within the historical range of the species that contain the essential physical or biological features that would aid in the reestablishment of populations under section 10(j) of the Act.

(10) Information regarding the need for other recovery tools such as safe harbor agreements, in addition to, or instead of, the designation of critical habitat, and why.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

All comments submitted electronically via *http://www.regulations.gov* will be presented on the website in their entirety as submitted. For comments submitted via hard copy, we will post your entire comment—including your personal identifying information—on *http://www.regulations.gov*. You may request at the top of your document that we withhold personal information such as your street address, phone number, or email address from public review; however, we cannot guarantee that we will be able to do so.

Comments and materials we receive and supporting documentation we used in preparing this proposed rule will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Previous Federal Actions

See the candy darter proposed listing rule (82 FR 46197; October 4, 2017) for a history of previous Federal actions prior to today's publication of this proposed rule.

Elsewhere in today's **Federal Register**, we published a final rule to list the candy darter as an endangered species under the Act.

Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the consultation requirements of section 7(a)(2) of the Act would apply, but even in the event of a destruction or adverse modification finding, the obligation of the Federal action agency and the landowner is not to restore or recover the species, but to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are

essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features within an area, we focus on the specific features that support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. We will determine whether unoccupied areas are essential for the conservation of the species by considering the life-history, status, and conservation needs of the species. This will be further informed by any generalized conservation strategy, criteria, or outline that may have been developed for the species to provide a substantive foundation for identifying which features and specific areas are essential to the conservation of the species and, as a result, the development of the critical habitat designation. For example, an area currently occupied by the species but that was not occupied at the time of listing may be essential to the conservation of the species and may be included in the critical habitat designation.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the species status assessment (SSA) report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act, (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species, and (3) section 9 of the Act's prohibitions on taking any individual of the species, including taking caused by actions that affect habitat. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available data at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species' conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist:

(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or

(2) Such designation of critical habitat would not be beneficial to the species. In determining whether a designation would not be beneficial, the factors the Service may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of ''critical habitat.''

There is no imminent threat of take attributed to collection or vandalism identified under Factor B for this species (82 FR 46197; October 4, 2017), and identification and mapping of critical habitat is not expected to initiate any such threat. In the absence of finding that the designation of critical habitat would increase threats to a species, we next determine whether such designation of critical habitat would not be beneficial to the species. In our proposed listing rule (82 FR 46197; October 4, 2017), that was informed by the SSA (Service 2017, entire), we determined that there are habitat-based threats to the candy darter species identified under Factor A (82 FR 46197, pp. 46200–46201). Therefore, we find that the designation of critical habitat would be beneficial to the candy darter through the provisions of section 7 of the Act. Because we have determined that the designation of critical habitat will not likely increase the degree of threat to the species and would be beneficial, we find that designation of critical habitat is prudent for the candy darter.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the candy darter is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where these species are located (Service 2018, entire). This and other information (Industrial Economics, Inc. (IEc) 2018, entire) represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for the candy darter (see below).

Physical or Biological Features

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas within the geographical area occupied by the species at the time of listing to designate as critical habitat, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. For example, physical features might include gravel of a particular size required for spawning, alkali soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic needed to support the life history of the species. In considering whether features are essential to the conservation of the species, the Service may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features (PBFs) essential to the conservation of the candy darter from studies of this species' habitat, ecology, and life history as described below. Additional information can be found in the final listing rule published elsewhere in today's **Federal Register**. We have determined that the following physical or biological features are essential to the conservation of the candy darter:

(1) Ratios or densities of nonnative species that allow for maintaining populations of candy darters.

(2) A blend of unembedded gravel and cobble that allows for normal breeding, feeding, and sheltering behavior.

(3) Adequate water quality characterized by seasonally moderated temperatures and physical and chemical parameters (*e.g.,* pH, dissolved oxygen levels, turbidity) that support normal behavior, growth, and viability of all life stages of the candy darter.

(4) An abundant, diverse benthic macroinvertebrate community (*e.g.,* mayfly nymphs, midge larvae, caddisfly larvae) that allows for normal feeding behavior.

(5) Sufficient water quantity and velocities that support normal behavior, growth, and viability of all life stages of the candy darter.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The overall habitat characteristics that are important for the candy darter include sufficiently stabilized forest stream banks throughout the watersheds such that water quality allows for normal feeding, breeding, and sheltering in an area with sufficiently low numbers of nonnative species (Service 2018, pp. 15–17, 22–25, 32–34). The features essential to the conservation of the candy darter may require special management considerations or protections to reduce the following threats: (1) Hybridization with the nonnative variegate darter (*Etheostoma variatum*); (2) general increase in water temperature, primarily attributed to land use changes; (3) changes in water chemistry, including, but not limited to, changes in pH levels and contamination with coliform bacteria; (4) habitat fragmentation primarily due to construction of barriers and impoundments; (5) excessive sedimentation and stream bottom embeddedness (the degree to which gravel, cobble, rocks, and boulders are surrounded by, or covered with, fine sediment particles); and (6) competition for habitat and other instream resources and predation from nonnative fishes.

Management activities that could ameliorate these threats include, but are not limited to: Use of best management practices (BMPs) designed to reduce sedimentation, erosion, and bankside destruction; protection of riparian corridors and retention of sufficient canopy cover along banks; reduction of other watershed disturbances that release sediments, pollutants, or nutrients into the water; public outreach requesting the public's assistance with stopping the movement of nonnative aquatic species; increased enforcement and/or outreach regarding existing regulations prohibiting the movement of bait fish; survey and monitoring to further characterize the extent and spread of hybridization with variegate darters; research to determine whether some environmental factors or set of factors might allow candy darters to persist in particular areas despite variegate darter introductions; research characterizing habitat conditions in historically extirpated candy darter sites to facilitate successful reintroduction efforts; research and development of tools and techniques that can be used to address the competitive behavior that allows for variegate darters to dominate candy darters, which leads to hybridization; and re-introductions of candy darters to historically extirpated areas and/or population augmentation of candy darters in sufficient numbers to outcompete variegate darters.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we did not find any areas that were essential for the conservation of the species.

The current distribution of the candy darter is much reduced from its historical distribution. We anticipate that recovery will require continued protection of existing populations and habitat, in addition to establishing populations in additional streams that more closely approximate its historical distribution to ensure there are adequate numbers of fish in stable populations and that these populations occur over a wide geographic area. These actions will help to ensure that catastrophic events, such as flooding or a contamination spill event, cannot simultaneously affect all known populations.

Sources of data for this species include the West Virginia Department of Natural Resources, Virginia Department of Game and Inland Fisheries, U.S. Geological Survey, published scientific literature and government reports, and unpublished data from researchers at the Virginia Polytechnic Institute, West Virginia University, and the University of Missouri. A complete list of specific sources is provided in the SSA report (Service 2018, pp. 68–74) and available online at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2018–0050.

Areas Occupied at the Time of Listing

The proposed critical habitat designation does not include all streams known to have been historically occupied by the species; instead, it focuses on occupied streams within the historical range that retain the necessary PBFs that allow for the maintenance and expansion of existing populations. The following streams have sections that meet the definition of areas occupied by the species (Service 2018, pp. 13, 56) at the time of listing:

- In the Greenbrier River watershed of West Virginia (WV)—the East and West Forks of the Greenbrier River, Little River of the West Fork, Little River of the East Fork, the ''Upper'' Greenbrier River (between Knapps Creek and the confluences of East and West Forks), Deer Creek, North Fork Deer Creek, Sitlington Creek, and Knapp Creek;
- In the Middle New River watershed of Virginia (VA)—Dismal Creek, Stony Creek, and Laurel Creek;
- In the Lower Gauley River watershed of WV—the ''Lower'' Gauley River;
- In the Upper New River watershed of VA—Cripple Creek; and
- In the Upper Gauley River watershed of WV—the headwaters of the Gauley River, Straight Creek, ''Upper'' Gauley River, Panther Creek, Williams River, Tea Creek, Cranberry River, Cherry River, North and South Forks of the Cherry River, and Laurel Creek.

There are no developed areas within the wetted portion of these streams.

Areas Outside of the Geographic Range at the Time of Listing

We are not proposing to designate any areas outside of the geographic range at the time of listing. However, in line with our conservation strategy, we intend to reestablish populations within the candy darter's historical range under section 10(j) of the Act or through other applicable voluntary conservation tools (*e.g.,* safe harbor agreements). Areas within the historical range that may be considered for repatriation include sections of Reed Creek, Pine Run, and Sinking Creek in VA; and sections of Indian Creek, Bluestone River, and Camp Creek in WV. We may consider these areas for repatriation because the candy darter is no longer present in these areas, these areas do not currently contain the variegate darter, the land use-based threats previously responsible for the candy darter's extirpation have been ameliorated, and repopulation of the candy darter in these areas would not be possible without human assistance because they are isolated from other currently occupied candy darter streams. We are seeking public input during the open comment period regarding other areas that are currently unoccupied within the historical range of the candy darter, contain the essential physical and biological features that support the candy darter's life-history processes, and/or could facilitate the reestablishment of populations under section 10(j) of the Act.

Summary of Criteria Used To Identify Critical Habitat

In summary, for areas within the geographic area occupied by the species at the time of listing, we propose critical habitat unit boundaries using the following approach:

(1) We delineated areas within the historical range that had positive survey data between the year 2000 and the time of listing (see Service 2018).

(2) We terminated stream segments at barriers, confluences, areas where genetically pure candy darters have been extirpated, other obvious unsuitable habitat, or a location selected based on expert knowledge of a lack of presence.

(3) We included connecting stream segments between occupied stream segments as long as the inclusion does not disagree with criterion (2) and there are no data to suggest that the candy darter is not present.

(4) If there are no data points (positive or negative occurrence), we did not include the segment.

(5) In the absence of other biologically meaningful termini, we established a buffer approximately 1-mile long from the last known positive survey point.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the candy darter. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We are proposing for designation as critical habitat lands that we have determined are occupied at the time of listing and contain one or more of the PBFs to support life-history processes essential to the conservation of the candy darter. Some units contain all of the identified PBFs and support multiple life-history processes. Some units contain only some of the PBFs necessary to support the candy darter's particular use of that habitat.

The critical habitat designation is defined by the maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *http://www.regulations.gov* under Docket No. FWS–R5–ES–2018–0050, on *https://www.fws.gov/northeast/candydarter/,* and at the field office responsible for the designation (see **FOR FURTHER INFORMATION CONTACT**, above).

Proposed Critical Habitat Designation

We are proposing to designate approximately 596 stream kilometers (skm) (370 stream miles (smi)) in five units as critical habitat for the candy

darter. The critical habitat areas we describe below constitute our best assessment of areas that meet the definition of critical habitat for the candy darter. The five areas we propose as critical habitat are: (1) Greenbrier Unit, (2) Middle New Unit, (3) Lower Gauley Unit, (4) Upper New Unit, and (5) Upper Gauley Unit. All stream reaches within each watershed that are proposed for designation were occupied at the time of listing. The approximate area of each proposed critical habitat unit is shown in the table below.

TABLE OF PROPOSED CRITICAL HABITAT UNITS FOR THE CANDY DARTER

Critical habitat unit	Land ownership	Unit size (stream length)	
		Miles	Kilometers
1. Greenbrier	Federal	78	126
	State	6	10
	Private	70	113
Unit Total		154	248
2. Middle New	Federal	14	22
	State	0	0
	Private	13	21
Unit Total		27	43
3. Lower Gauley	State	0	0
	State	0	0
	Private	0	0
Unit Total		2	3
4. Upper New	Federal	0	0
	State	0	0
	Private	5	8
Unit Total		5	8
5. Upper Gauley	Federal	90	145
	State	0	0
	Private	92	148
Unit Total		182	293
Grand Total		370	596

Note: Area sizes may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for candy darter, below. In all instances, the units are occupied (see Areas Occupied at the Time of Listing, above); the State of VA or WV, as applicable, owns the stream water and stream bottoms; and the lands described below are those adjacent to the designated critical habitat stream areas.

Unit 1: Greenbrier

The Greenbrier Unit consists of six subunits in Pocahontas County, WV. The occupied streams are adjacent to primarily Federal land, with some private land and one State owned parcel. Candy darter have been surveyed in the Greenbrier Unit as recently as 2014 (Service 2018, p. 48). See details below.

Unit 1a: East Fork of the Greenbrier River, Pocahontas County, WV

Unit 1a includes approximately 31.2 skm (19.4 smi) of the East Fork of the Greenbrier River from a point approximately 3.2 skm (2.0 smi) upstream of the Bennett Run confluence, downstream to the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, WV; and approximately 12.2 skm (7.6 smi) of the Little River from a point 3.2 skm (2.0 smi) upstream of the power line right-of-way, downstream to the confluence of the Little River and the East Fork of the Greenbrier River. The land adjacent to this unit is mostly forested interspersed with small communities, low density residences, and agricultural fields along the lower portion of the East Fork of the Greenbrier River. Approximately 26.2 skm (16.3 smi) of Unit 1a is within the Monongahela National Forest with the remainder located almost entirely adjacent to private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Candy darters occur at multiple sites in this unit (Service 2018, p. 28) . Unit 1a contributes to the redundancy of the Greenbrier metapopulation.

Unit 1b: West Fork of the Greenbrier River, Pocahontas County, WV

Unit 1b includes approximately 29.9 skm (18.6 smi) of the West Fork of the Greenbrier River from the Public Road 44 crossing, downstream to the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, WV; and approximately 14.2 skm (8.8 smi) of the Little River from a point approximately 1.6 skm (1.0 smi) upstream of the Lukins Run confluence, downstream to the confluence of the Little River and the West Fork of the Greenbrier River. The land adjacent to this unit is almost entirely forested interspersed with a few residences and agricultural fields along the lower portion of the West Fork of the Greenbrier River near the town of Durbin, WV. Approximately 43.2 skm (26.8 smi) of Unit 1b is within the

Monongahela National Forest with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys found candy darters at multiple sites in this unit (Service 2018, p. 28). Unit 1b contributes to the redundancy of the Greenbrier metapopulation.

Unit 1c: Upper Greenbrier River, Pocahontas County, WV

Unit 1c includes approximately 69.3 skm (43.1 smi) of the Greenbrier River from the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, WV, downstream to the confluence of Knapp Creek at Marlinton, WV. The land adjacent to this unit is mostly forested; however, several small communities with residences and light commercial development, along with scattered rural residences and agricultural fields, occur at various locations. Approximately 47.5 skm (29.5 smi) of Unit 1c is within the Monongahela National Forest and the Seneca State Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Survey data indicate candy darters are present in the upper and lower portions of this unit (Service 2018, p. 28). While survey data for the intervening section are lacking, candy darters may occur where suitable habitat is present. Unit 1c contributes to the redundancy of the Greenbrier metapopulation and provides connectivity between the other Greenbrier watershed populations.

Unit 1d: Deer Creek, Pocahontas County, WV

Unit 1d includes approximately 21.2 skm (13.2 smi) of Deer Creek from the confluence of Deer Creek and Saulsbury Run, downstream to the confluence with the Greenbrier River; and approximately 16.3 skm (10.1 smi) of North Fork from a point approximately 1.6 skm (1.0 smi) upstream of the Elleber Run confluence, downstream to the confluence of North Fork and Deer Creek. The lower half of the land adjacent to this unit is mostly forested, while the upper portion contains low density residences and agricultural fields. Approximately 10.0 skm (6.2 smi) of Unit 1d is within the Monongahela National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys collected candy darters at two locations in this unit (Service 2018, p. 28). Unit 1d contributes to the redundancy of the Greenbrier metapopulation.

Unit 1e: Sitlington Creek, Pocahontas County, WV

Unit 1e includes approximately 10.1 skm (6.3 smi) of Sitlington Creek from the confluence of Galford Run and Thorny Branch, downstream to the confluence with the Greenbrier River. Some of the riparian area of Unit 1e is forested; however, the majority of the land adjacent to this unit is agricultural fields and widely scattered residences. Approximately 1.2 skm (0.7 smi) of Unit 1e is within the Monongahela National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Candy darters at several locations in this unit (Service 2018, p. 28). Unit 1e contributes to the redundancy of the Greenbrier metapopulation.

Unit 1f: Knapp Creek, Pocahontas County, WV

Unit 1f includes approximately 43.9 skm (27.3 smi) of Knapp Creek from a point approximately (0.1 smi) west of the WV Route 84 and Public Road (PR) 55 intersection, downstream to the confluence with the Greenbrier River at Marlinton, WV. The land adjacent to this unit is largely forested; however, low density residential and agricultural fields occur in much of the upstream portions. The land surrounding the lowest section of Unit 1f is dominated by residential and commercial development. Approximately 7.2 skm (4.5 smi) of Unit 1f is within the Monongahela National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys indicate candy darters at several locations in this unit (Service 2018, p. 28). Unit 1f contributes to the redundancy of the Greenbrier metapopulation.

Unit 2: Middle New

The Middle New Unit comprises three stream subunits in Bland and Giles Counties, VA. The occupied streams are adjacent to a mix of Federal and private land. Candy darter have been surveyed in the Middle New Unit as recently as 2016 (Service 2018, p. 48). See details below.

Unit 2a: Dismal Creek, Bland and Giles Counties, VA

Unit 2a includes approximately 4.2 skm (2.6 smi) of Dismal Creek from the confluence with Standrock Branch, downstream to the confluence of Dismal Creek and Walker Creek. The land adjacent to this unit is almost entirely forested, with some scattered residences and small agricultural fields. Approximately 3.2 skm (2.0 smi) of Unit 2a is within the George Washington and Jefferson National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys indicate a small candy darter population that contributes to the representation and redundancy of the species (Service 2018, p. 28).

Unit 2b: Stony Creek, Giles County, VA

Unit 2b includes approximately 34.1 skm (21.2 smi) of Stony Creek from a point approximately 2.4 skm (1.5 smi) upstream of North Fork Mountain Road, downstream to the confluence with the New River. The land adjacent to this unit is almost entirely forested, with some scattered residences, a large underground lime mine, a processing plant, and a railroad spur line along the downstream portion. Approximately 19.2 skm (11.9 smi) of Unit 2b is within the George Washington and Jefferson National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys indicate candy darters at multiple locations within this unit. Unit 2b is the most robust population in Virginia and contributes to the representation and redundancy of the species (Service 2018, p. 28).

Unit 2c: Laurel Creek, Bland County, VA

Unit 2c includes approximately 5.1 skm (3.2 smi) of Laurel Creek from a point approximately 0.8 skm (0.5 smi) upstream of the unnamed pond, downstream to the confluence of Laurel Creek and Wolf Creek. The unit passes through a forested gap in a ridgeline; however, the riparian zone is dominated by Interstate Highway 77, U.S. Highway 52, and residential and commercial development. Unit 2c is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys found candy darters at several locations within this unit (Service 2018, p. 28). Unit 2c contributes to the representation and redundancy of the species.

Unit 3: Lower Gauley, ''Lower'' Gauley River, Nicholas County, WV

Unit 3 includes approximately 2.9 skm (1.8 smi) of the Gauley River from

the base of the Summersville Dam, downstream to the confluence of Collison Creek. The land adjacent to this unit is entirely forested, with the exception of parking areas and infrastructure at the base of the Summersville Dam. The entirety of Unit 3 is within the National Park Service's (NPS') Gauley River National Recreation Area and the U.S. Army Corps of Engineer's (Corps') Summersville Recreation Area. Candy darters are abundant in the tailwaters of the dam. Unit 3 maintains the only candy darter population remaining in the Lower Gauley watershed and contributes to the representation and redundancy of the species and candy darters were surveyed as recently as 2014 (Service 2018, pp. 28 & 48).

Unit 4: Upper New, Cripple Creek, Wythe County, VA

Unit 4 includes approximately 7.9 skm (4.9 smi) of Cripple Creek from a point approximately (2.0 smi) upstream of the State Road 94 bridge, downstream to the confluence of Cripple Creek and the New River. The land adjacent to this unit is primarily low density residences and agricultural fields, although some small segments pass through wooded parcels. The stream in Unit 4 is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys found candy darters at several locations within this unit as recently as 2016 (Service 2018, pp. 28 & 48). This is the only known candy darter population in the Upper New River watershed, and this unit contributes to the representation and redundancy of the species.

Unit 5: Upper Gauley

The Upper Gauley Unit consists of six stream subunits in Nicholas, Greenbrier, Pocahontas, and Webster Counties, WV. The occupied streams are adjacent to a mix of Federal and private land. Candy darter have been surveyed in the Upper Gauley Unit as recently as 2014 (Service 2018, p. 48). See details below.

Unit 5a: Gauley Headwaters, Webster County, WV

Unit 5a includes approximately 23.2 skm (37.3 smi) of the Gauley River from the North and South Forks of the Gauley River, downstream to the confluence of the Gauley River and the Williams River at Donaldson, WV; and 2.9 skm (1.8 smi) of Straight Creek from its confluence with the Gauley River to a point approximately 2.9 skm (1.8 smi) upstream of the confluence. The land adjacent to this unit is mostly forested; however, aerial imagery (Environmental Systems Research Institute (ESRI) 2015; ESRI 2016; ESRI 2017) shows forest clearings with varying degrees of regrowth, indicating ongoing timber harvests in some tributary stream systems. Other human development in the watershed consists primarily of scattered residences and roads, mostly in the valley adjacent to the Gauley River. Approximately 9.0 skm (5.6 smi) of Unit 5a is within the Monongahela National Forest. The remainder of the unit is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys of Unit 5a captured candy darters at multiple locations (Service 2018, p. 28). The unit contributes to the redundancy of the Upper Gauley metapopulation.

Unit 5b: Upper Gauley River, Nicholas and Webster Counties, WV

Unit 5b includes approximately 43.8 skm (27.2 smi) of the Gauley River from the confluence of the Gauley and Williams Rivers at Donaldson, WV, downstream to a point approximately 1.6 skm (1.0 smi) upstream of the Big Beaver Creek confluence. The land adjacent to this unit is mostly forested; however, aerial imagery (ESRI 2015; ESRI 2016; ESRI 2017) show forest clearings with varying degrees of regrowth, indicating ongoing timber harvests in some areas. Other human development consists primarily of low-density residential areas and small communities with some commercial facilities. Small agricultural fields are associated with some of the scattered residences. Approximately 14.6 skm (9.2 smi) of Unit 5b is within the Monongahela National Forest and/or adjacent to land owned by the Corps. The streams in the remainder of the unit are adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Surveys of Unit 5b captured candy darters at several locations (Service 2018, p. 28). The unit provides connectivity between other candy darter streams in the Upper Gauley watershed and contributes to the redundancy of the Upper Gauley metapopulation.

Unit 5c: Panther Creek, Nicholas County, WV

Unit 5c includes approximately 16.3 skm (10.1 smi) of Panther Creek from a point approximately 1.1 skm (0.7 smi) upstream of the Grassy Creek Road crossing, downstream to the confluence with the Gauley River. The unit is mostly forested; however, aerial imagery (ESRI 2015; ESRI 2016; ESRI 2017) show forest clearings with varying degrees of regrowth, indicating ongoing timber harvests in much of the upland areas. Other human development consists of the occasional residence and small agricultural field in the creek valley, and the Richwood Municipal Airport located on an adjacent ridge. The streams in Unit 5c are adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. While survey data are sparse for this unit, candy darters occur within Panther Creek, and the stream maintains suitable habitat for the species; thus, this unit contributes to the redundancy of the Upper Gauley metapopulation (Service 2018, p. 28).

Unit 5d: Williams River, Pocahontas and Webster Counties, WV

Unit 5d includes approximately 52.4 skm (32.6 smi) of the Williams River from the confluence with Beaverdam Run, downstream to the confluence of the Williams River and the Gauley River at Donaldson, WV; and 5.1 skm (3.2 smi) of Tea Creek from a point on Lick Creek approximately 2.7 skm (1.7 smi) upstream of the Lick Creek confluence, downstream to the Tea Creek confluence with the Williams River. The land adjacent to this unit is almost entirely forested with just a few residences and small agricultural fields at the lower portion of the river. The streams in Unit 5d are entirely within the Monongahela National Forest. Survey data indicate candy darters are present at the upper and lower portions of this unit. While data are sparse for the majority of the intervening stretch, we assume, based on the available evidence, that the habitat is suitable for the species (Service 2018, p. 28). Unit 5d contributes to the redundancy of the Upper Gauley metapopulation.

Unit 5e: Cranberry River, Nicholas and Webster Counties, WV

Unit 5e includes approximately 39.3 skm (24.4 smi) of the Cranberry River from the confluence of the North and South Forks of the Cranberry River, downstream to the confluence of the Cranberry River and the Gauley River. The land adjacent to this unit is almost entirely forested, and the stream is entirely within the Monongahela National Forest. Survey data indicate candy darters are present at the upper and lower portions of this unit. While survey are sparse for the intervening stretch, we assume, based on the available evidence, that the habitat is suitable for the species (Service 2018, p. 28). Unit 5e contributes to the

redundancy of the Upper Gauley metapopulation.

Unit 5f: Cherry River, Greenbrier and Nicholas Counties, WV

Unit 5f includes approximately 16.7 skm (10.4 smi) of Cherry River from the confluence of the North and South Forks of the Cherry River, downstream to the confluence of the Cherry River and the Gauley River; approximately 28.0 skm (17.4 smi) of the North Fork Cherry River from the Pocahontas Trail crossing, downstream to the confluence of the North and South Forks of the Cherry River; approximately 26.2 skm (16.3 smi) of the South Fork Cherry River from a point approximately 0.5 skm (0.3 smi) south of County Road 29/4 in VA, downstream to the confluence of the North and South Forks of the Cherry River; and approximately 24.9 skm (15.5 smi) of Laurel Creek from a point approximately 0.3 skm (0.2 smi) west of Cold Knob Road, downstream to the confluence of Laurel Creek the Cherry River. The land adjacent to this unit is mostly forested with scattered residences along the lower portion of the Cherry River. The town of Richwood, WV, with residential and commercial development and an industrial sawmill, is at the confluence of the North and South Forks of the Cherry River. The North and South Forks of the Cherry River are almost entirely forested; however, aerial imagery (ESRI 2015; ESRI 2016; ESRI 2017) show forest clearings with varying degrees of regrowth, indicating ongoing timber harvests in several locations. There are scattered residences on Laurel Creek and some evidence of recent timber harvests; otherwise, the land adjacent to this section of Unit 1f is mostly forested. Approximately 29.1 skm (18.1 smi) of Unit 5f is within the Monongahela National Forest. The remainder is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like. Survey data indicate candy darters are well distributed throughout most of this unit (Service 2018, p. 28). Unit 5f contributes to the redundancy of the Upper Gauley metapopulation.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final rule adopting a new definition of ''destruction or adverse modification'' on February 11, 2016 (81 FR 7214). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, tribal, local, or private lands that require a Federal permit (such as a permit from the Corps under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat, and actions on State, tribal, local, or private lands that are not federally funded or authorized, do not require section 7 consultation.

As a result of section 7 consultation, we document compliance with the requirements of section 7(a)(2) through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where we have listed a new species or subsequently designated critical habitat that may be affected and the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law). Consequently, Federal agencies sometimes may need to request reinitiation of consultation with us on actions for which formal consultation has been completed, if those actions with discretionary involvement or control may affect subsequently listed species or designated critical habitat.

Application of the ''Adverse Modification'' Standard

The key factor related to the adverse modification determination is whether, with implementation of the proposed Federal action, the affected critical habitat would continue to serve its intended conservation role for the species. Activities that may destroy or adversely modify critical habitat are those that result in a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of the candy darter. Such alterations may include, but are not limited to, those that alter the PBFs essential to the conservation of these species or that preclude or significantly delay development of such features. As discussed above, the role of critical habitat is to support PBFs essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation.

Activities that may affect critical habitat, when carried out, funded, or authorized by a Federal agency, should result in consultation for the candy darter. These activities include, but are not limited to:

(1) Actions that would promote or facilitate the movement of variegate darters (or other nonnative aquatic species). Such activities could include, but are not limited to, the transfer of surface water across watershed boundaries and the modification or removal of dams that are currently limiting the spread of variegate darters where they have been introduced. These activities could further decrease the abundance of the candy darter through hybridization with the nonnative variegate darter.

(2) Actions that would significantly increase water temperature or sedimentation and stream bottom embeddedness. Such activities could include, but are not limited to, land use changes that result in an increase in sedimentation, erosion, and bankside destruction or the loss of the protection of riparian corridors and leaving insufficient canopy cover along banks.

(3) Actions that would significantly alter water chemistry. Such activities could include, but are not limited to, release of chemicals, biological pollutants, or heated effluents into the surface water or connected groundwater at a point source or by dispersed release (nonpoint source). These activities could alter water conditions to levels that are beyond the tolerances of the candy darter and result in direct or cumulative adverse effects to these individuals and their life cycles.

(4) Actions that would contribute to further habitat fragmentation. Such activities include, but are not limited to, construction of barriers that impede the instream movement of the candy darter (*e.g.,* dams, culverts, or weirs). These activities can isolate populations that are more at risk of decline or extirpation as a result of genetic drift, demographic or environmental stochasticity, and catastrophic events.

(5) Actions that would contribute to nonnative competition for habitat and other instream resources and to predation. Possible actions could include, but are not limited to, stocking of nonnative fishes or other related actions. These activities can introduce predators or affect the growth, reproduction, and survival of the candy darter through competition for resources.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making that determination, the statute on its face and the legislative history are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

We have not considered any areas for exclusion from critical habitat. However, the final decision on whether to exclude any areas will be based on the best scientific data available at the time of the final designation, including information we obtain during the comment period and information about the economic impact of designation. Accordingly, we have prepared a draft economic analysis (DEA) concerning the proposed critical habitat designation, which is available for review and comment (see **ADDRESSES**, above).

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.'' The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing and other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat (Service 2018b). The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the candy darter (Industrial Economics, Incorporated (IEc) 2018). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out the geographic areas in which the critical habitat designation is unlikely to result in probable incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. The screening analysis filters out particular areas of critical habitat that are already

subject to such protections and are therefore unlikely to incur incremental economic impacts. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. The screening analysis also assesses whether units are unoccupied by the species and may require additional management or conservation efforts as a result of the critical habitat designation for the species, because the additional management or conservation efforts may incur incremental economic impacts. This screening analysis, combined with the information contained in our IEM, is what we consider our draft economic analysis (DEA) of the proposed critical habitat designation for the candy darter and is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O.s' regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the candy darter, first we identified, in the IEM dated April 18, 2018, probable incremental economic impacts associated with the following categories of activities: (1) Watershed and stream restoration activities (Natural Resources Conservation Service (NRCS), U.S. Forest Service (USFS), Service, Corps, Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA)); (2) timber harvest and vegetation management (USFS); (3) prescribed fire (USFS); (4) construction and management of recreation improvement activities (USFS, NPS); (5) coal mining (Office of Surface Mining (OSM)); (6) pipeline and utility crossings (Corps, Federal Energy Regulatory Commission (FERC)); (7) road and bridge construction and maintenance (Corps, Federal Highway Administration (FHWA)); (8) pesticide use (USFS, FERC, FHWA); (9) abandoned mine reclamation (OSM); (10) emergency response activities (FEMA); and (11) oil and gas exploration (Corps). We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat affects only activities conducted, funded, permitted, or authorized by Federal agencies. In areas where the candy darter is present, Federal agencies already are required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that will result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the candy darter's critical habitat. The following specific circumstances in this case help to inform our evaluation: (1) The essential PBFs identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm to constitute jeopardy to the candy darter would also likely adversely affect the essential PBFs of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

We have identified and delineated five proposed critical habitat units, totaling approximately 596 skm (370 smi), that are currently (*i.e.,* at the time of listing) occupied by the candy darter. These units are considered occupied year-round for the purposes of consultation based on current survey data. In these areas, any actions that may affect the species or its habitat would also affect designated critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the candy darter. Because we are proposing only the designation of occupied critical habitat, we anticipate a relatively small increase in administrative costs related to the proposed critical habitat designation. While this additional analysis will require time and resources by both the Federal action agency and the Service, it is believed that, in most circumstances, these costs would predominantly be administrative in nature and would not be significant.

The entities most likely to incur incremental costs are parties to section 7 consultations, in this case, only Federal action agencies. We do not anticipate any costs to State or local agencies, or impacts on property values related to the public's perception of additional regulation, because we do not expect the designation of critical habitat for the candy darter to result in changes to Virginia or West Virginia fishing regulations, or other local regulations (IEc 2018, pp. 14–15).

The probable incremental economic impacts of the candy darter critical habitat designation are expected to be limited to additional administrative effort resulting from a small number of future section 7 consultations. This is due to the fact that (1) All proposed critical habitat stream reaches are considered to be occupied by the species; (2) within occupied habitat, regardless of whether critical habitat is designated, all projects with a Federal nexus will already be subject to the section 7 requirement; and (3) during section 7 consultation, project modifications that would be recommended to avoid adverse modification would already be requested to avoid jeopardizing the continued existence of the species. There are no forecasted incremental costs associated with project modifications (IEc 2018, p. 8).

At approximately $10,000 or less per consultation, to reach the threshold of $100 million of incremental administrative impacts in a single year, critical habitat designation would have to result in more than 11,000 consultations in a single year (IEc 2018, p. 11). No more than 91 candy darter consultations (31 technical assistance, 55 informal, 1 formal, 2 reinitiated formal, and 1 programmatic) are anticipated in any given year (IEc 2018, pp. 12–13). Units 1 (Greenbrier Watershed) and 5 (Upper Gauley Watershed) have the highest potential costs, due in part to the higher densities of occupied candy darter streams relative to the other units and the anticipated consultation workload

associated with the Monongahela National Forest (Unit 1) and planned road construction (Unit 5). However, the estimated incremental costs of critical habitat designation for the candy darter in the first year are unlikely to exceed $200,000 (2018 dollars) (IEc 2018, p. 15). Thus, the annual administrative burden will not reach $100 million.

As we stated earlier, we are soliciting data and comments from the public on the DEA and all aspects of the proposed rule and our required determinations. We may revise the proposed rule or supporting documents to incorporate or address information we receive during the public comment period. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Exclusions

Exclusions Based on Economic Impacts

Under section 4(b)(2) of the Act, we consider the economic impacts of specifying any particular area as critical habitat. To consider economic impacts, we prepared an analysis of the probable economic impacts of the proposed critical habitat designation and related factors.

During the development of a final designation, we will consider any additional economic impact information we receive through the public comment period, and as such areas may be excluded from the final critical habitat designation under section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19.

Exclusions Based on National Security Impacts or Homeland Security Impacts

Under section 4(b)(2) of the Act, we consider whether there are lands owned or managed by the Department of Defense where a national security impact might exist. In preparing this proposal, we have determined that the lands adjacent to the proposed designation of critical habitat for candy darter are not owned or managed by the Department of Defense or Department of Homeland Security, and, therefore, we anticipate no impact on national security. Consequently, the Secretary is not intending to exercise his discretion to exclude any areas from the final designation based on impacts on national security.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security. We consider a number of factors including whether there are permitted conservation plans covering the species in the area such as HCPs, safe harbor agreements, or candidate conservation agreements with assurances, or whether there are nonpermitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of tribal conservation plans and partnerships and consider the government-to-government relationship of the United States with tribal entities. We also consider any social impacts that might occur because of the designation.

Although we have determined that there are currently no HCPs or other management plans for the candy darter and the proposed designation does not include any tribal lands or trust resources, we are aware of management plans within the candy darter's range such as the Monongahela National Forest Land and Resource Management Plan and forest plans for the George Washington and Thomas Jefferson National Forests. At this time, we anticipate no impact on tribal lands, partnerships, or HCPs from this proposed critical habitat designation. Accordingly, the Secretary does not intend to exercise his discretion to exclude any areas from the designation based on other relevant impacts.

Consideration of Reestablishing Populations Within the Historical Range Under Section 10(j) of the Act

We believe that the best way to facilitate reintroductions of candy darter within the historical range where the essential PBFs can be found will be to use the authorities under section 10(j) of the Act. We have developed a conservation strategy for the candy darter, part of which identified the need to reestablish candy darter populations within areas of its historical range. These areas could include Reed Creek, Pine Run, and Sinking Creek in VA; and sections of Indian Creek, Bluestone River, and Camp Creek in WV. Because the candy darter is extirpated from these areas and natural repopulation is not possible without human assistance, use of a 10(j) rule may be one appropriate tool to achieve this recovery objective. An overview of the process to establish an experimental population under section 10(j) of the Act is described below.

Section 10(j) of the Act enables us to designate certain populations of federally listed species that are released into the wild as ''experimental.'' The circumstances under which this designation can be applied are: (1) The population is geographically separate from nonexperimental populations of the same species (*e.g.,* the population is reintroduced outside the species' current range but within its probable historical range); and (2) we determine that the release will further the conservation of the species. Section 10(j) is designed to increase our flexibility in managing an experimental population by allowing us to treat the population as threatened, regardless of the species' status elsewhere in its range. Threatened status gives us more discretion in developing and implementing management programs and special regulations for a population, and allows us to develop any regulations we consider necessary to provide for the conservation of a threatened species. In situations where we have experimental populations, certain section 9 prohibitions (*e.g.,* harm, harass, capture) that apply to endangered and threatened species may no longer apply, and a rule issued under section 4(d) of the Act can be developed that contains the prohibitions and exceptions necessary and appropriate to conserve that species. This flexibility allows us to manage the experimental population in a manner that will ensure that current and future land, water, or air uses and activities will not be unnecessarily restricted and that the population can be managed for recovery purposes.

When we designate a population as experimental, section 10(j) of the Act requires that we determine whether that population is either essential or nonessential to the continued existence of the species, based on the best available information. Nonessential experimental populations located outside National Wildlife Refuge System or National Park System lands are treated, for the purposes of section 7 of the Act, as if they are proposed for listing. Thus, for nonessential experimental populations, only two provisions of section 7 would apply outside National Wildlife Refuge System and National Park System lands: Section 7(a)(1), which requires all Federal agencies to use their authorities to conserve listed species, and section 7(a)(4), which requires Federal agencies to informally confer with the Service on actions that are likely to jeopardize the continued existence of a proposed species. Section 7(a)(2) of the Act, which requires Federal agencies to ensure that their activities are not likely to jeopardize the continued existence of a listed species, would not apply except

on National Wildlife Refuge System and National Park System lands. Experimental populations determined to be ''essential'' to the survival of the species would remain subject to the consultation provisions of section 7(a)(2) of the Act.

To establish an experimental population, we must issue a proposed rule and consider public comments on the proposed rule prior to publishing a final rule. In addition, we must comply with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*). Also, our regulations require that, to the extent practicable, a rule issued under section 10(j) of the Act represent an agreement between the Service, the affected State and Federal agencies, and persons holding any interest in land that may be affected by the establishment of the experimental population (see 50 CFR 17.81(d)).

The flexibility gained by establishment of a nonessential experimental population through section 10(j) would be reduced if there is a designation of critical habitat that overlaps it. This is because Federal agencies would still be required to consult with us on any actions that may adversely modify critical habitat. In fact, section 10(j)(2)(C)(ii) of the Act states that critical habitat shall not be designated under the Act for any experimental population determined to be not essential to the continued existence of a species.

We wish to reestablish the candy darter in areas of its historical range. We strongly believe that to achieve recovery for the candy darter we would need the flexibility provided for in section 10(j) of the Act to help ensure the success of reestablishing the candy darter in suitable unoccupied areas within the historical range. Use of section 10(j) is meant to encourage local cooperation through management flexibility. Critical habitat is often viewed negatively by the public because it is not well understood and there are many misconceptions about how it affects private landowners. It is important for recovery of this species that we have the support of the public when we move towards meeting the recovery goals. Therefore, we conclude that the best way to facilitate reintroduction into unoccupied portions of the candy darter range is to garner support of private landowners adjacent to potential reintroduction areas through the management flexibility provided by 10(j) of the Act.

In summary, we believe that establishing nonessential experimental populations under Section 10(j) of the Act within the historical range will be the most effective means of achieving recovery for the candy darter. Establishing nonessential experimental populations will greatly benefit the overall recovery of the candy darter by allowing us to move forward using the flexibility and greater public acceptance of section 10(j) of the Act to reestablish the candy darter in other portions of its historical range where it no longer occurs. This is likely one of the most important steps in reaching recovery of this species, and we believe that section 10(j) is the best tool to achieve this objective. Thus, we believe that establishing a nonessential experimental population in unoccupied areas will be beneficial in conserving the species within historical range. We intend to initiate rulemaking regarding a section 10(j) rule for the candy darter in the near future.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of six individuals (and received responses from four) with expertise in darters; fisheries, population, or landscape ecology; genetics and conservation genetics; and/or speciation and conservation biology, regarding the species status assessment (SSA) report (Service 2018), which informed this proposed rule. The SSA report for the candy darter is a compilation of the best scientific and commercial data available concerning the status of the species, including the past, present, and future threats to this species. A team of Service biologists prepared the SSA report. The purpose of peer review is to ensure that our designation is based on scientifically sound data, assumptions, and analyses. We will consider all comments and information we receive during the comment period on this proposed rule during our preparation of a final determination. Accordingly, the final decision may differ from this proposal.

Public Hearings

Section 4(b)(5) of the Act provides for one or more public hearings on this proposal, if requested. Requests must be received by the date specified in **DATES** and sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings, and how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order (E.O.) 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Executive Order 13771

This rule is not an E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because this rule is not significant under E.O. 12866.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not

have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

The Service's current understanding of the requirements under the RFA, as amended, and following recent court decisions, is that Federal agencies are only required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself, and, therefore, are not required to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies will be directly regulated by this designation. There is no requirement under RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated if we adopt this rule as proposed, the Service certifies that, if made final, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that the designation of this proposed critical habitat would significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this proposed rule would significantly or uniquely affect small governments because the waters being proposed for critical habitat designation are owned by the States of Virginia and West Virginia. These government entities do not fit the definition of ''small government jurisdiction.'' Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the candy darter in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures or restrictions

on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for the candy darter would not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we request information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies in Virginia and West Virginia. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule would not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary to the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist these local governments in long-range planning (because these local governments would no longer have to wait for case-by-case section 7 consultations to occur).

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the elements of physical or biological features essential to the conservation of the species. The designated areas of critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. We determined that there are no tribal lands that were occupied by the candy darter at the time of listing that contain the features essential for conservation of the species, and no tribal lands unoccupied by the candy darter that are essential for the conservation of the species. Therefore, we are not proposing to designate critical habitat for the candy darter on any tribal lands.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of references cited in this rulemaking is available on the

internet at *http://www.regulations.gov* and upon request from the West Virginia Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Service's Species Assessment Team, the West Virginia Ecological Services Field Office, and the Southwest Virginia Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.95, amend paragraph (e) by adding an entry for ''Candy Darter (*Etheostoma osburni*)'' immediately following the entry for ''Amber Darter (*Percina antesella*),'' to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(e) *Fishes.*

* * * * *

Candy Darter (***Etheostoma osburni***)

(1) Critical habitat units are depicted for Bland, Giles, and Wythe Counties, Virginia, and Nicholas, Pocahontas, Greenbrier, and Webster Counties, West Virginia, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of the candy darter consist of the following components:

(i) Ratios or densities of nonnative species that allow for maintaining populations of candy darters.

(ii) Blend of unembedded gravel and cobble that allows for normal breeding, feeding, and sheltering behavior.

(iii) Adequate water quality characterized by seasonally moderated temperatures and physical and chemical parameters (*e.g.,* pH, dissolved oxygen levels, turbidity) that support normal behavior, growth, and viability of all life stages of the candy darter.

(iv) Abundant, diverse benthic macroinvertebrate community (*e.g.,* mayfly nymphs, midge larvae, caddisfly larvae) that allows for normal feeding behavior.

(v) Sufficient water quantity and velocities that support normal behavior, growth, and viability of all life stages of the candy darter.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of this rule.

(4) *Critical habitat map units.* The provided maps were made using the geographic projection GCS_North_American_1983 coordinate system. Four spatial layers are included as background layers. We used two political boundary layers indicating the State and county boundaries within the United States available through ArcMap Version 10.5 software by ESRI. The roads layer displays major interstates, U.S. highways, State highways, and county roads in the Census 2000/TIGER/Line dataset provided by the U.S. Census Bureau, and available through ArcMap Version 10.5 software. Lastly, the hydrologic data used to indicate river and stream location are a spatial layer of rivers, streams, and small tributaries from the National Hydrology Database (NHD) Plus Version 2 database. This database divides the United States into a number of zones, and the zones that include the area where candy darter critical habitat is indicated are the Ohio-05 hydrologic zone and the Mid Atlantic-02 hydrologic zone. The maps provided display the critical habitat in relation to State and county boundaries, major roads and highways, and connections to certain rivers and streams within the larger river network. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at *https://www.fws.gov/northeast/candydarter/,* at *http://www.regulations.gov* at Docket No. FWS–R5–ES–2018–0050, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) *Note:* Index map of candy darter critical habitat units follows:

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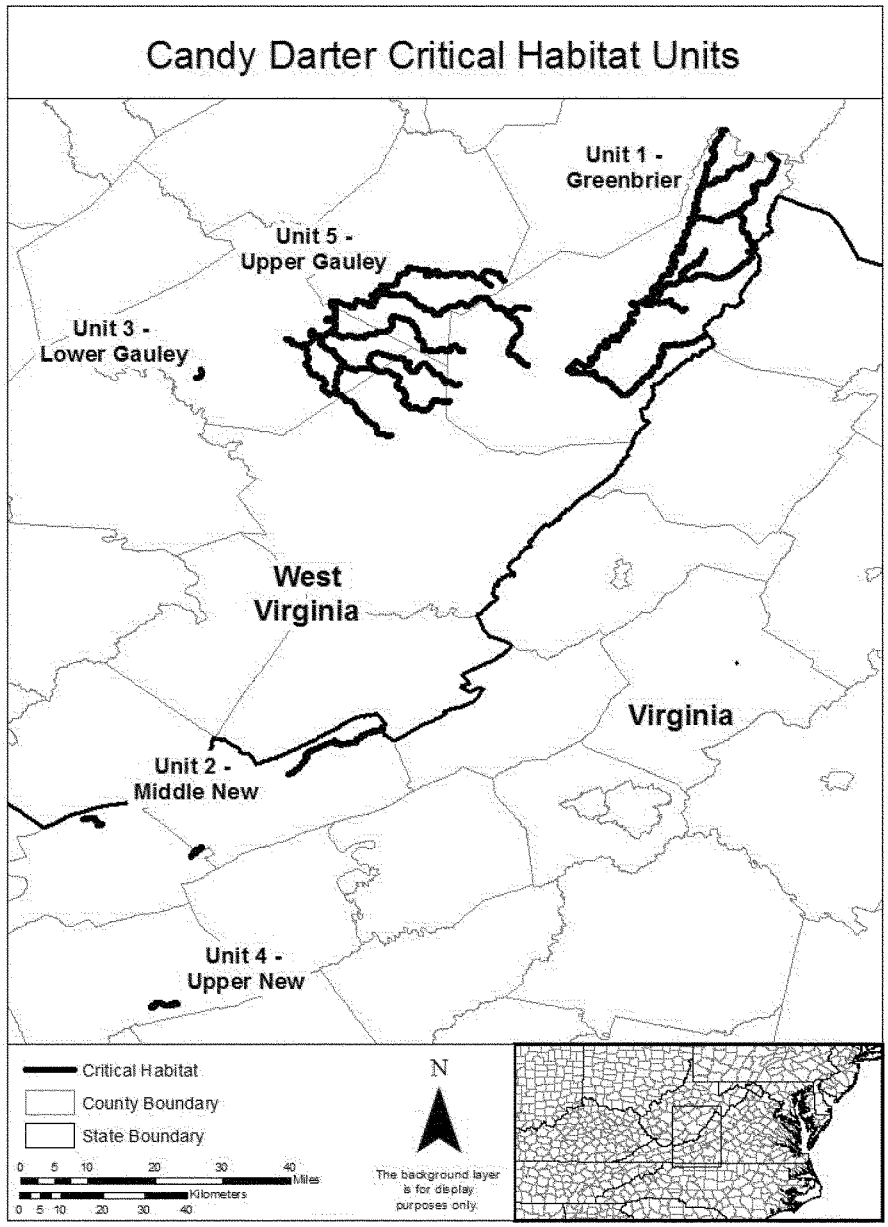
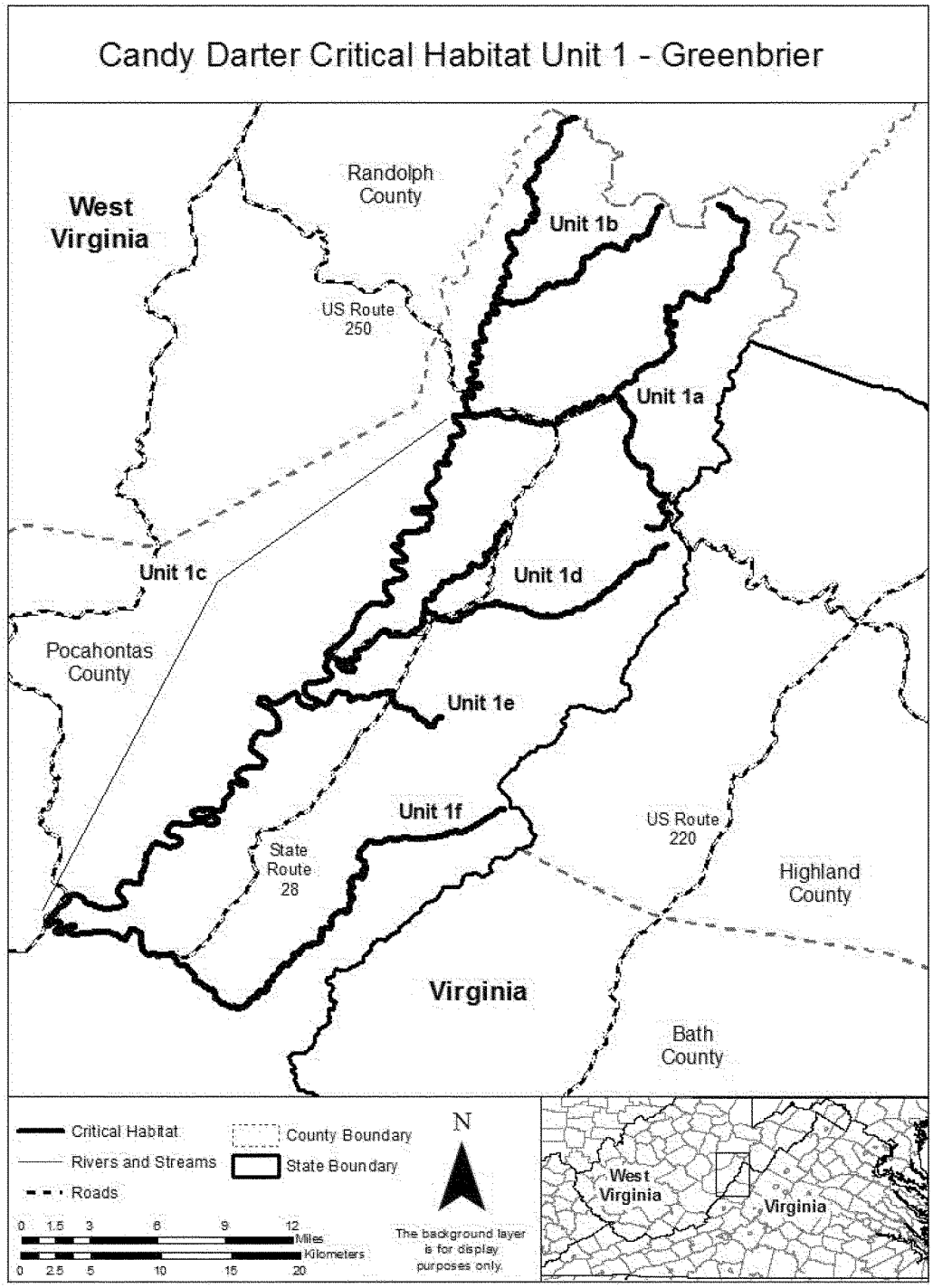


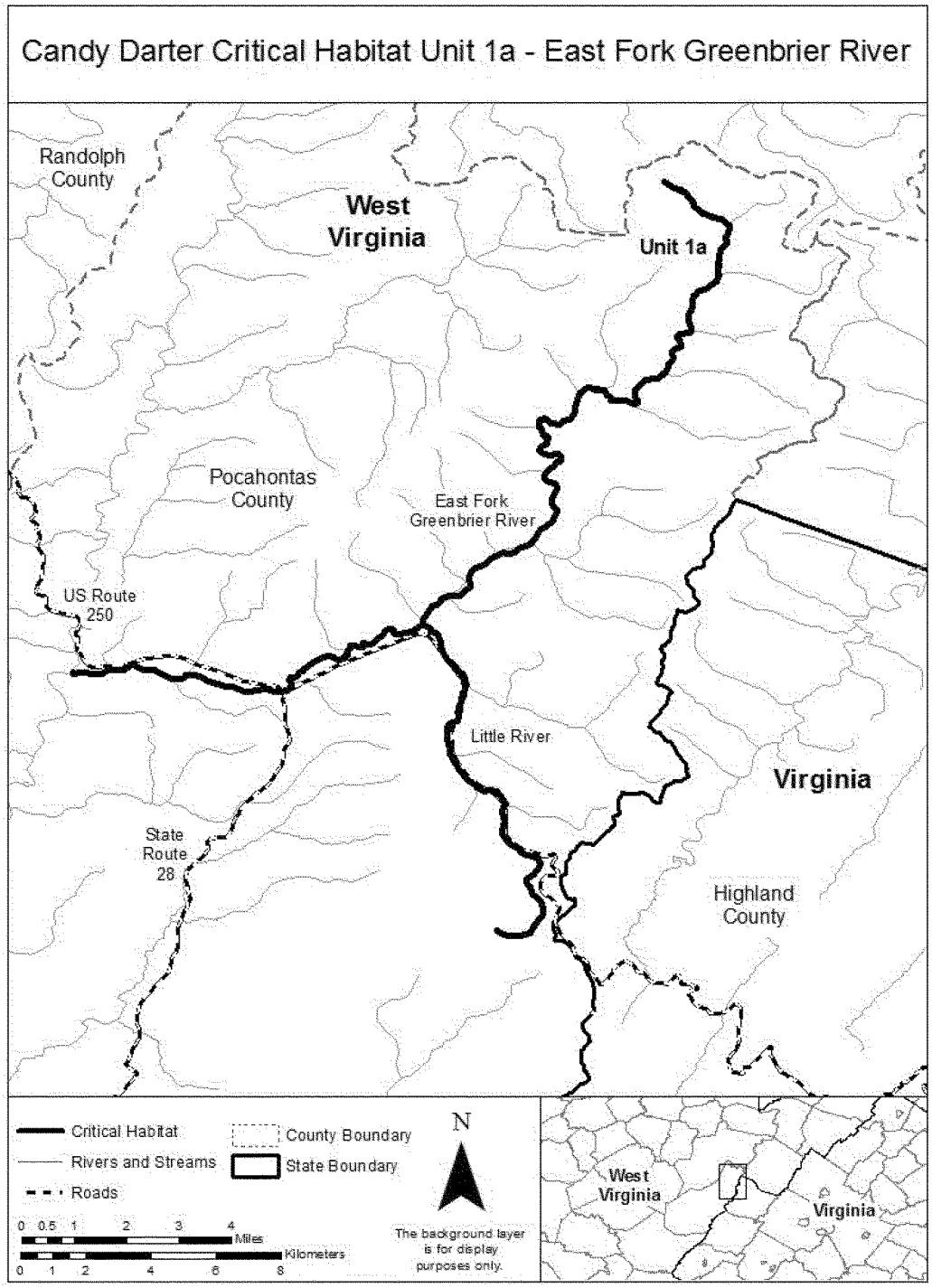
(6) Index map of Unit 1—Greenbrier follows:



(7) Unit 1a: East Fork of Greenbrier River, Pocahontas County, West Virginia.

(i) *General description:* Unit 1a consists of approximately 31.2 stream kilometers (skm) (19.4 stream miles (smi)) of the East Fork of the Greenbrier River from a point approximately 3.2 skm (2.0 smi) upstream of the Bennett Run confluence, downstream to the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, West Virginia; and approximately 12.2 skm (7.6 smi) of the Little River from a point 3.2 skm (2.0 smi) upstream of the power line right-of-way, downstream to the confluence of the Little River and the East Fork of the Greenbrier River. Approximately 26.2 skm (16.3 smi) of Unit 1a is within the Monongahela National Forest with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

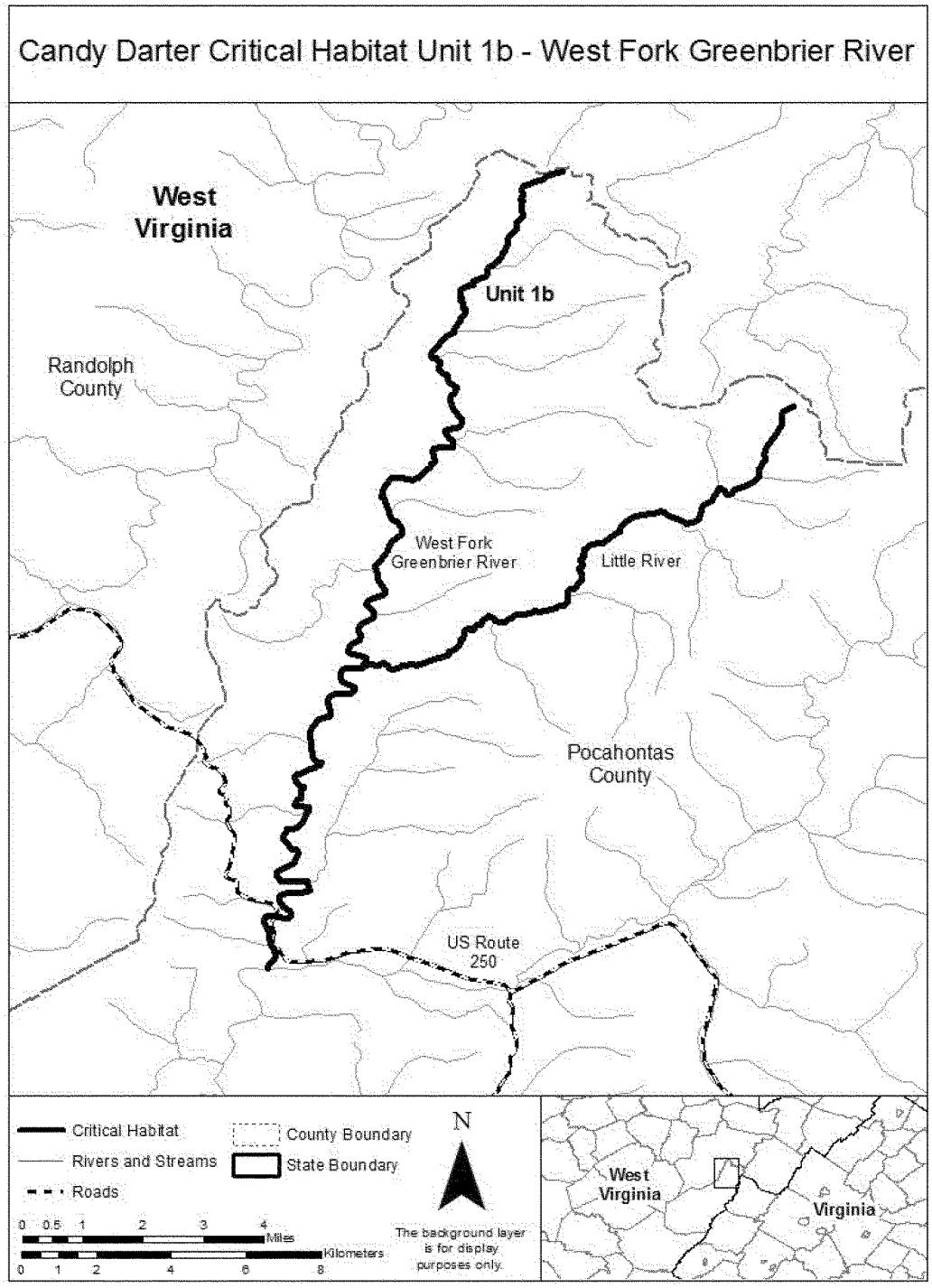
(ii) Map of Unit 1a, East Fork of Greenbrier River, follows:



(8) Unit 1b: West Fork of Greenbrier River, Pocahontas County, West Virginia.

(i) *General description:* Unit 1b includes approximately 29.9 skm (18.6 smi) of the West Fork of the Greenbrier River from the Public Road 44 crossing, downstream to the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, West Virginia; and approximately 14.2 skm (8.8 smi) of the Little River from a point approximately 1.6 skm (1.0 smi) upstream of the Lukins Run confluence, downstream to the confluence of the Little River and the West Fork of the Greenbrier River. Approximately 43.2 skm (26.8 smi) of Unit 1b is within the Monongahela National Forest with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

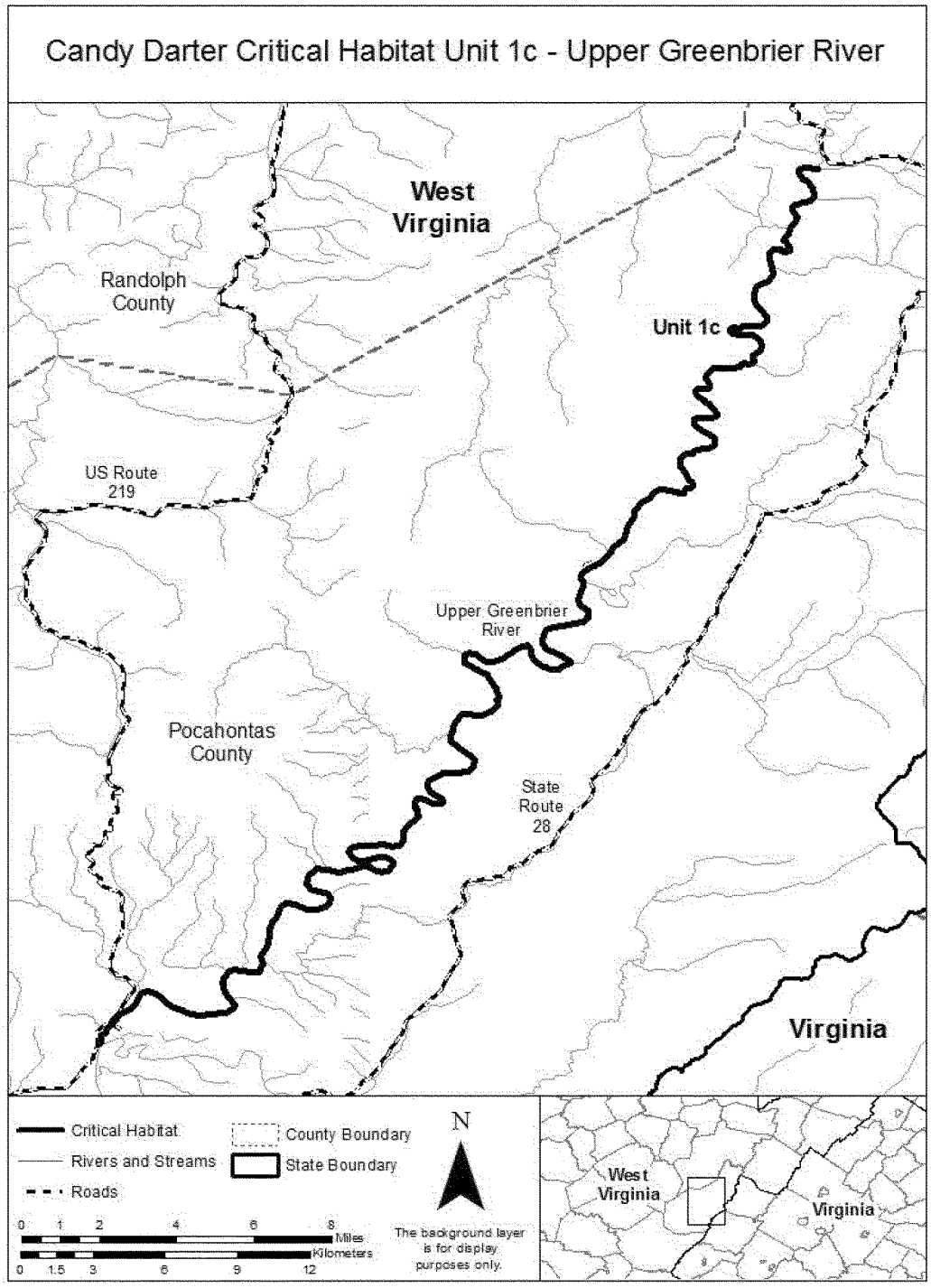
(ii) Map of Unit 1b, West Fork of Greenbrier River, follows:



(9) Unit 1c: Upper Greenbrier River, Pocahontas County, West Virginia.

(i) *General description:* Unit 1c includes approximately 69.3 skm (43.1 smi) of the Greenbrier River from the confluence of the East Fork and West Fork of the Greenbrier River at Durbin, West Virginia, downstream to the confluence of Knapp Creek at Marlinton, West Virginia. Approximately 47.5 skm (29.5 smi) of Unit 1c is within the Monongahela National Forest and the Seneca State Forest, with the remainder adjacent to located almost entirely on private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

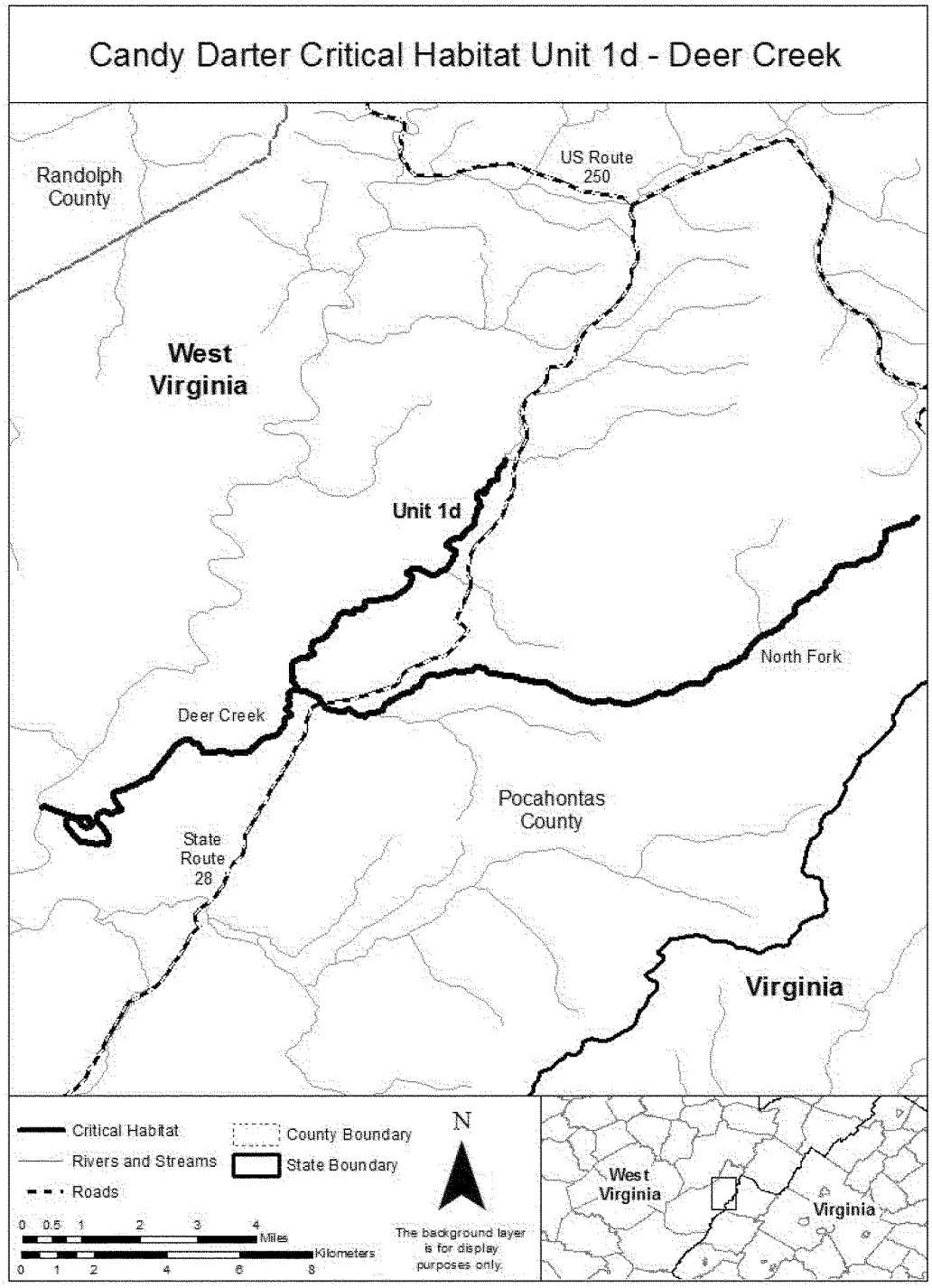
(ii) Map of Unit 1c, Upper Greenbrier River, follows:



(10) Unit 1d: Deer Creek, Pocahontas County, West Virginia.

(i) *General description:* Unit 1d includes approximately 21.2 skm (13.2 smi) of Deer Creek from the confluence of Deer Creek and Saulsbury Run, downstream to the confluence with the Greenbrier River; and approximately 16.3 skm (10.1 smi) of North Fork from a point approximately 1.6 skm (1.0 smi) upstream of the Elleber Run confluence, downstream to the confluence of North Fork and Deer Creek. Approximately 10.0 skm (6.2 smi) of Unit 1d is within the Monongahela National Forest, with the remainder adjacent to almost entirely on private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

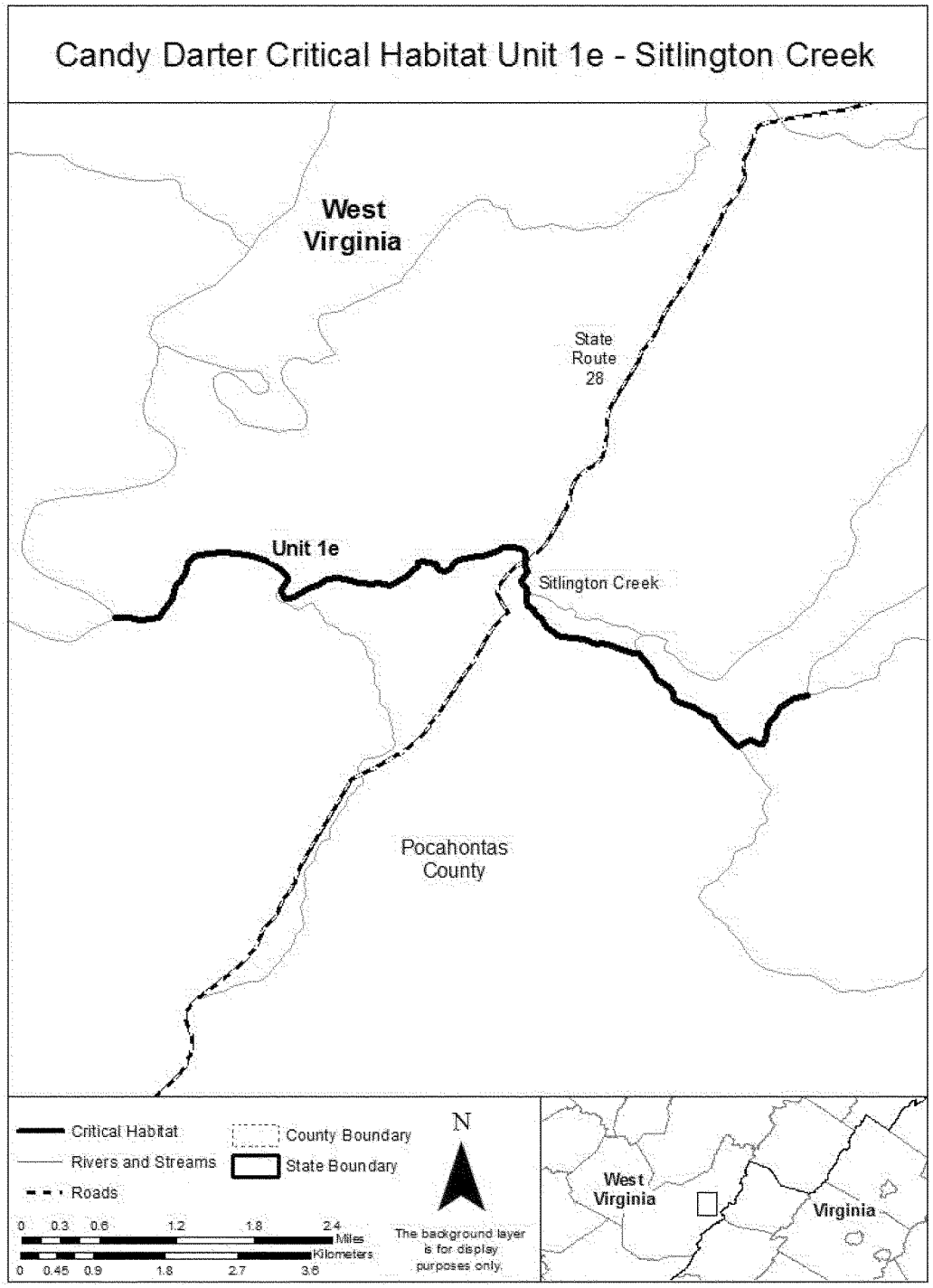
(ii) Map of Unit 1d, Deer Creek, follows:



(11) Unit 1e: Sitlington Creek, Pocahontas County, West Virginia.

(i) *General description:* Unit 1e includes approximately 10.1 skm (6.3 smi) of Sitlington Creek from the confluence of Galford Run and Thorny Branch, downstream to the confluence with the Greenbrier River. Approximately 1.2 skm (0.7 smi) of Unit 1e is within the Monongahela National Forest, with the remainder adjacent to almost entirely on private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

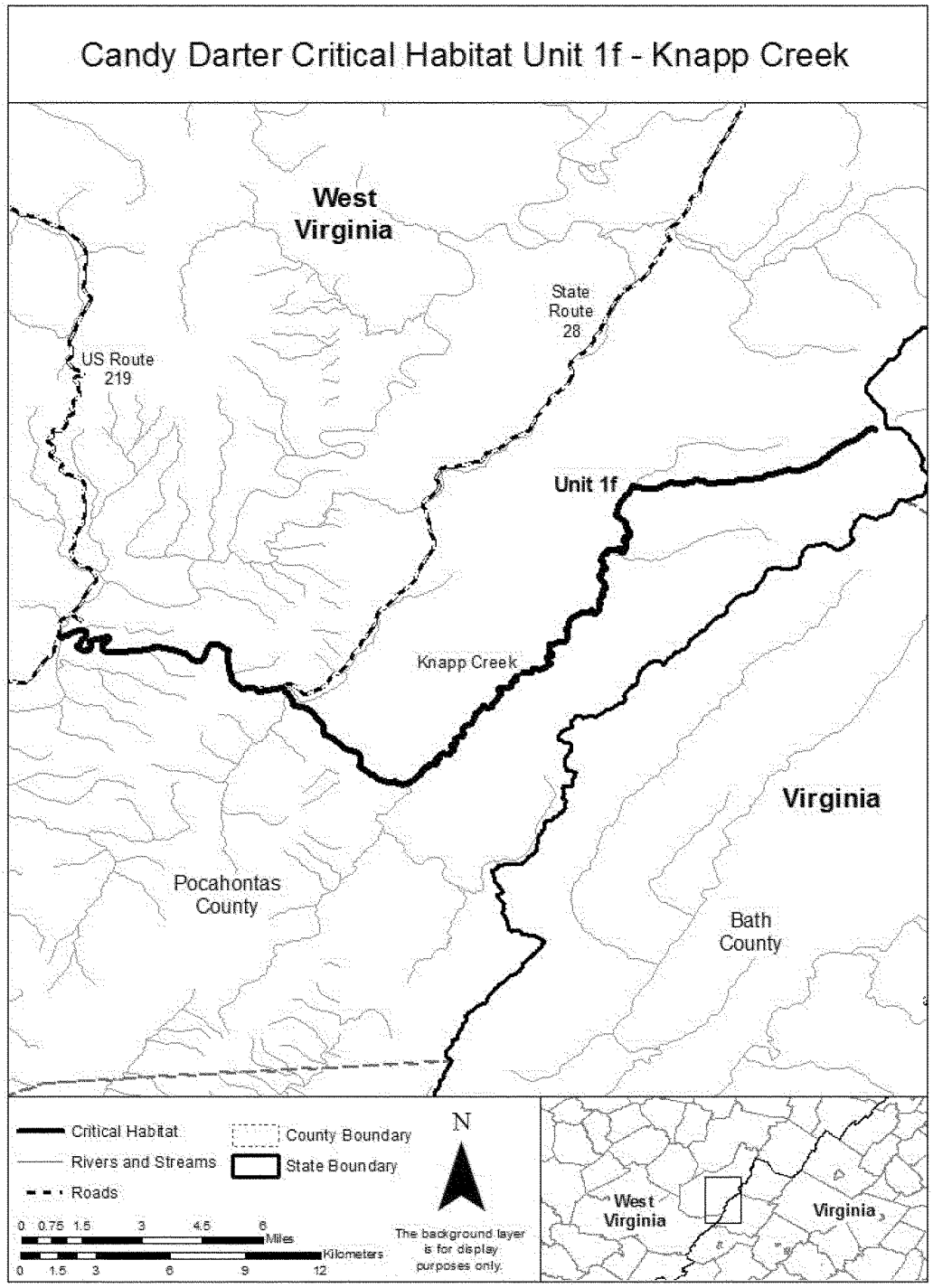
(ii) Map of Unit 1e, Sitlington Creek, follows:



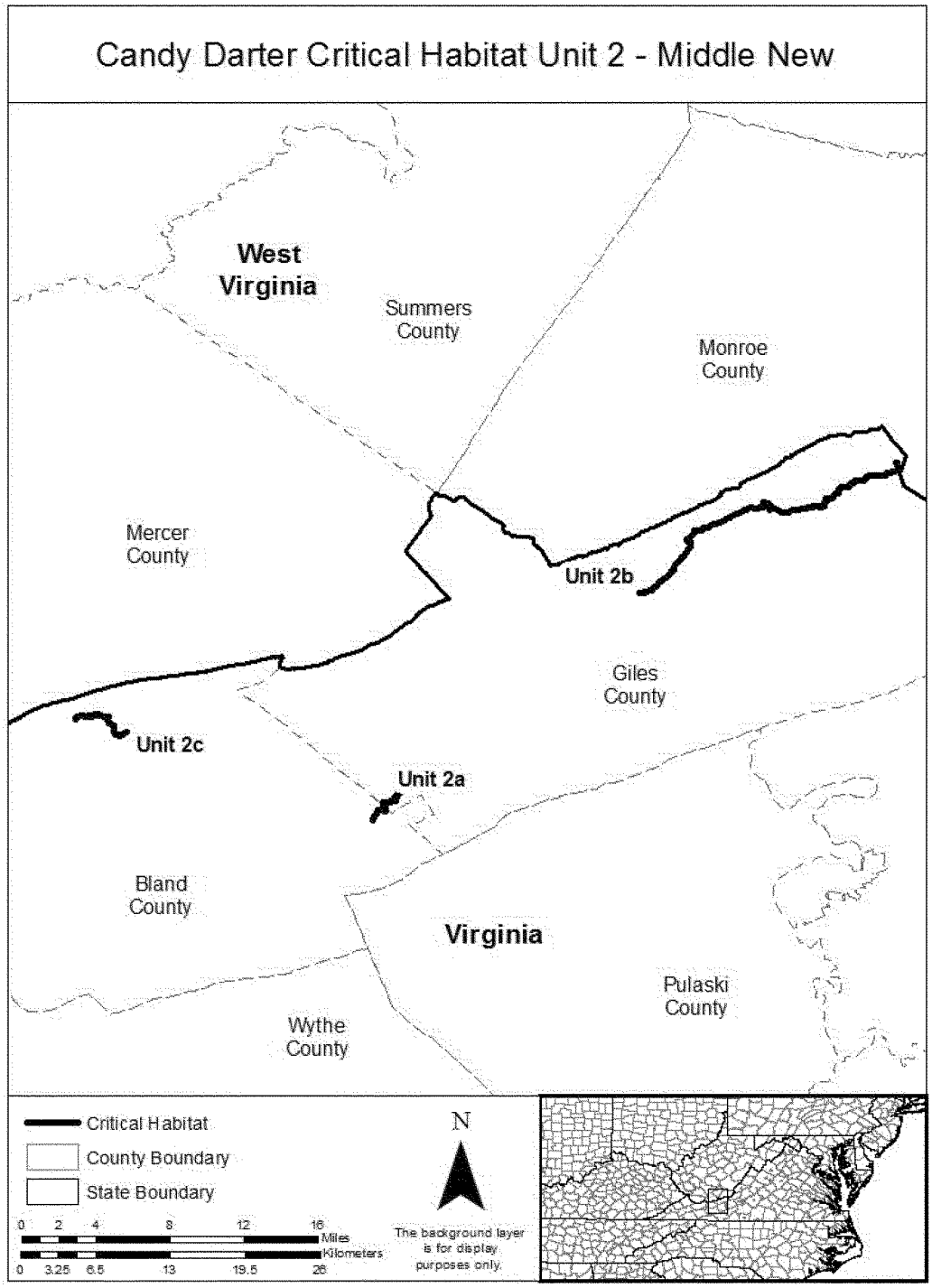
(12) Unit 1f: Knapp Creek, Pocahontas County, West Virginia.

(i) *General description:* Unit 1f includes approximately 43.9 skm (27.3 smi) of Knapp Creek from a point approximately (0.1 smi) west of the WV Route 84 and Public Road 55 intersection, downstream to the confluence with the Greenbrier River at Marlinton, West Virginia. Approximately 7.2 skm (4.5 smi) of Unit 1f is within the Monongahela National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

(ii) Map of Unit 1f, Knapp Creek, follows:



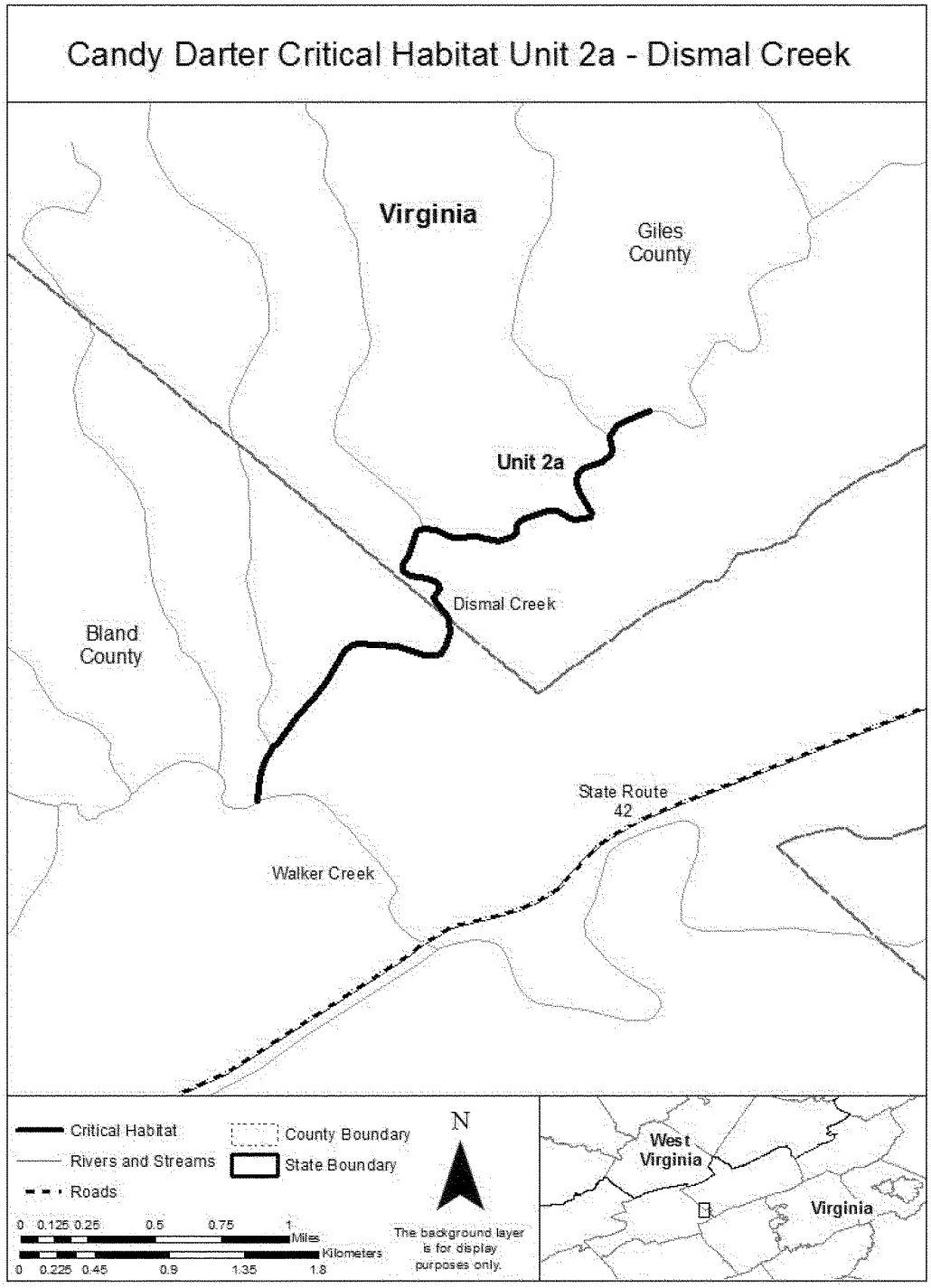
(13) Index map of Unit 2—Middle New follows:



(14) Unit 2a: Dismal Creek, Bland and Giles Counties, Virginia.

(i) *General description:* Unit 2a includes approximately 4.2 skm (2.6 smi) of Dismal Creek from the confluence with Standrock Branch, downstream to the confluence of Dismal Creek and Walker Creek. Approximately 3.2 skm (2.0 smi) of Unit 2a is within the George Washington and Jefferson National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

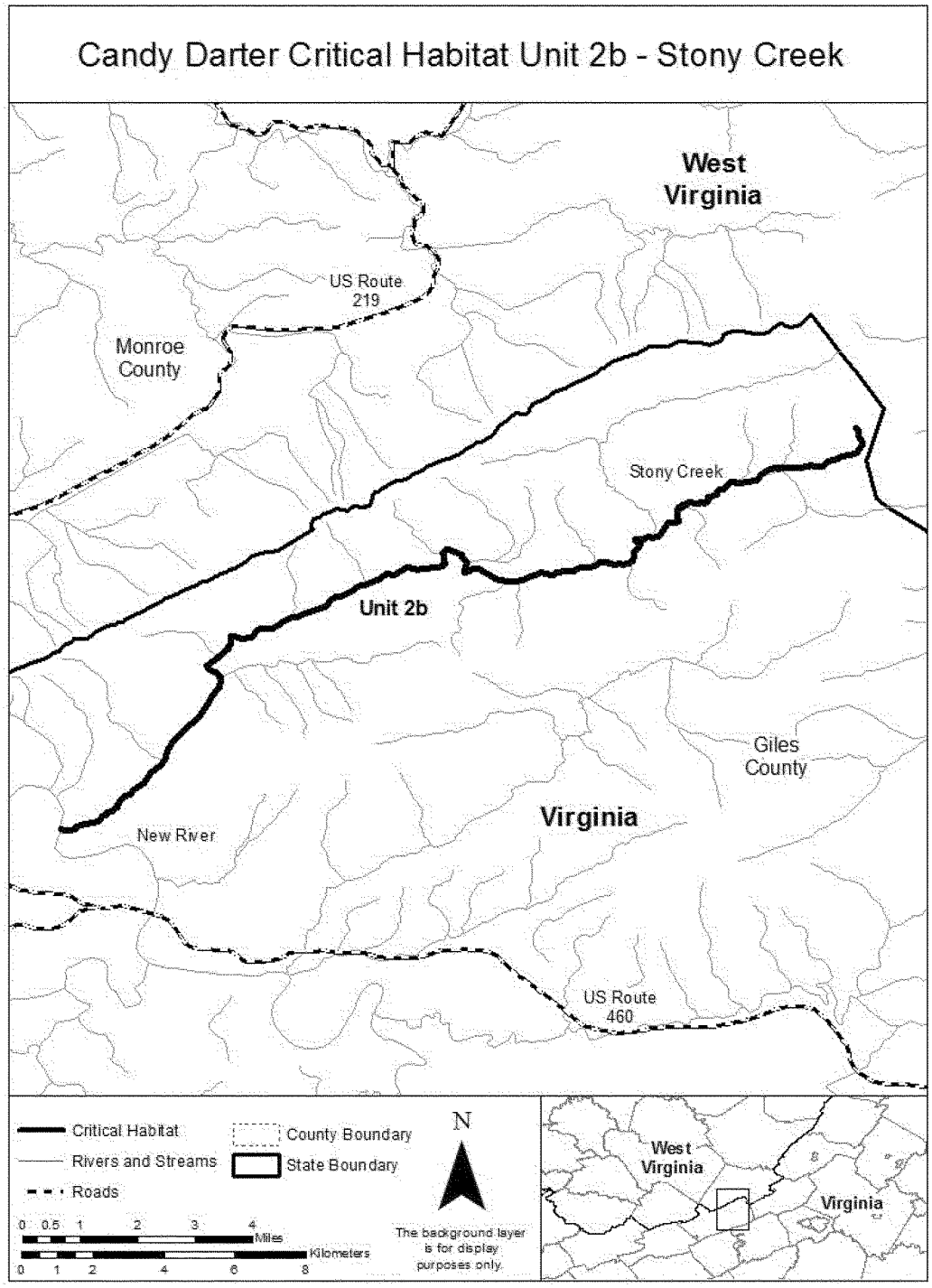
(ii) Map of Unit 2a, Dismal Creek, follows:



(15) Unit 2b: Stony Creek, Giles County, Virginia.

(i) *General description:* Unit 2b includes approximately includes approximately 34.1 skm (21.2 smi) of Stony Creek from a point approximately 2.4 skm (1.5 smi) upstream of North Fork Mountain Road, downstream to the confluence with the New River. Approximately 19.2 skm (11.9 smi) of Unit 2b is within the George Washington and Jefferson National Forest, with the remainder adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

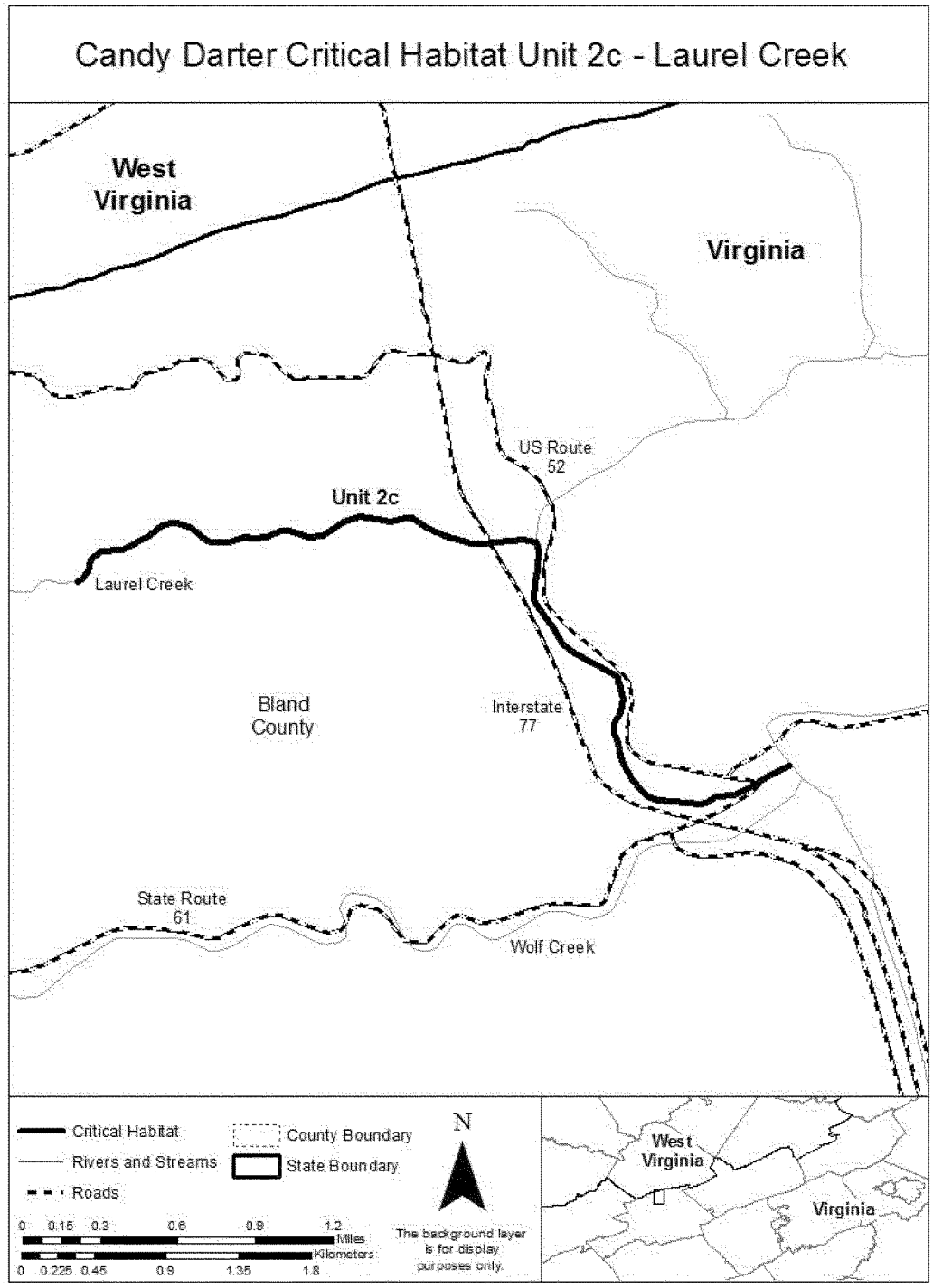
(ii) Map of Unit 2b, Stony Creek, follows:



(16) Unit 2c: Laurel Creek, Bland County, Virginia.

(i) *General description:* Unit 2c includes approximately 5.1 skm (3.2 smi) of Laurel Creek from a point approximately 0.8 skm (0.5 smi) upstream of the unnamed pond, downstream to the confluence of Laurel Creek and Wolf Creek. Unit 2c is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

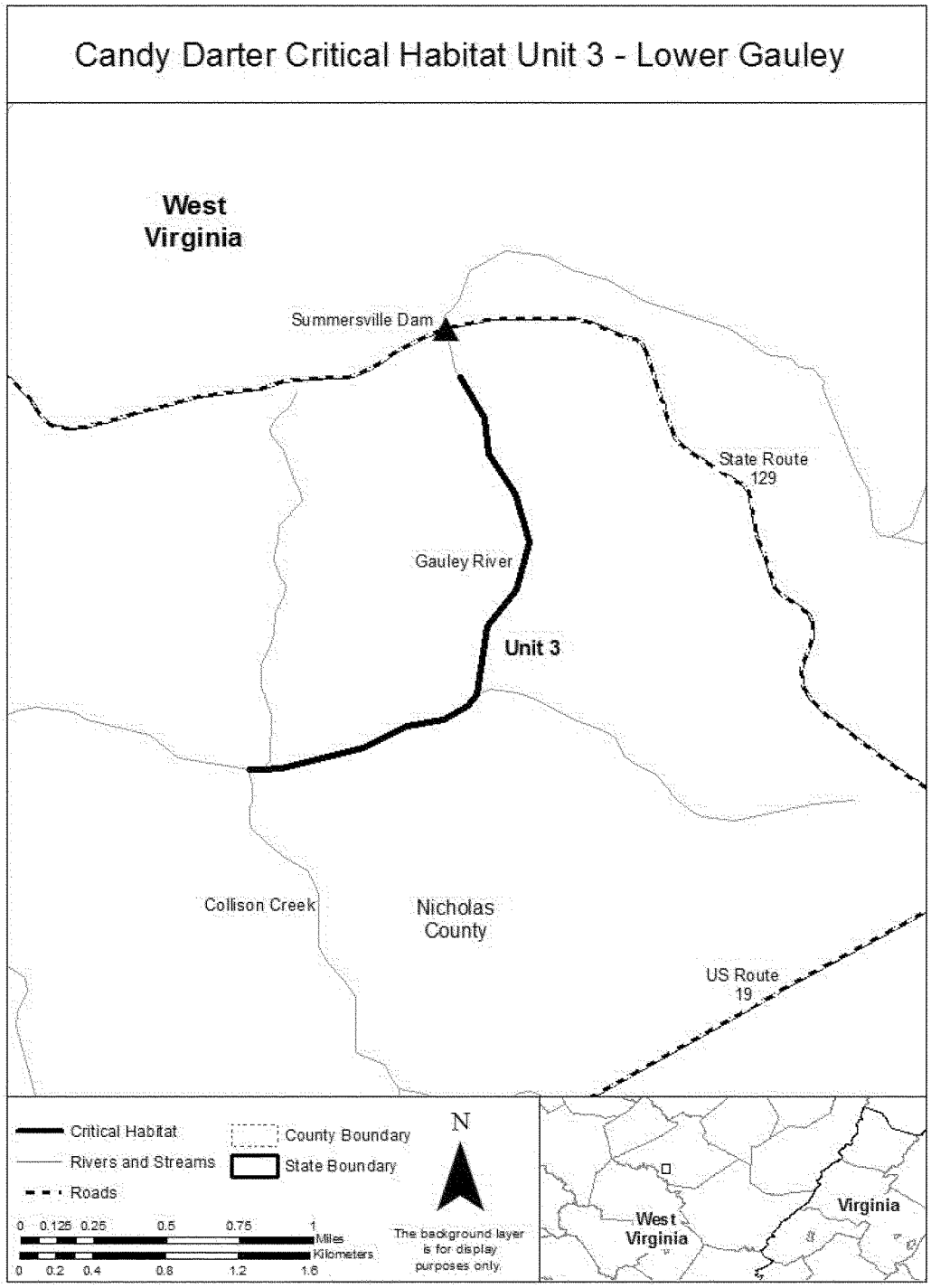
(ii) Map of Unit 2c, Laurel Creek, follows:



(17) Unit 3: Lower Gauley, ''Lower'' Gauley River, Nicholas County, West Virginia.

(i) *General description:* Unit 3 includes approximately 2.9 skm (1.8 smi) of the Gauley River from the base of the Summersville Dam, downstream to the confluence of Collison Creek. The entirety of Unit 3 is within the National Park Service's Gauley River National Recreation Area and the U.S. Army Corps of Engineer's Summersville Recreation Area.

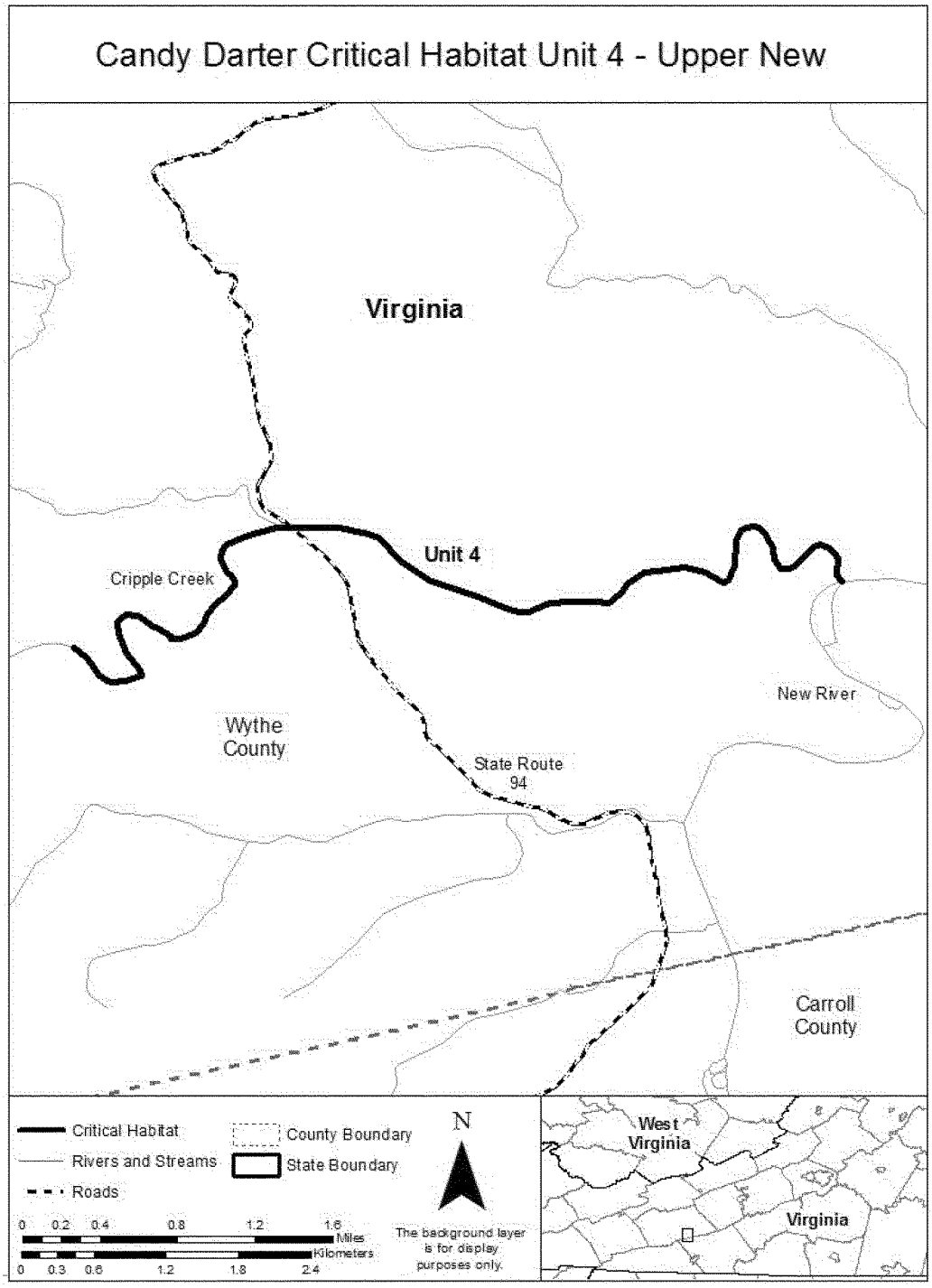
(ii) Map of Unit 3, Lower Gauley, follows:



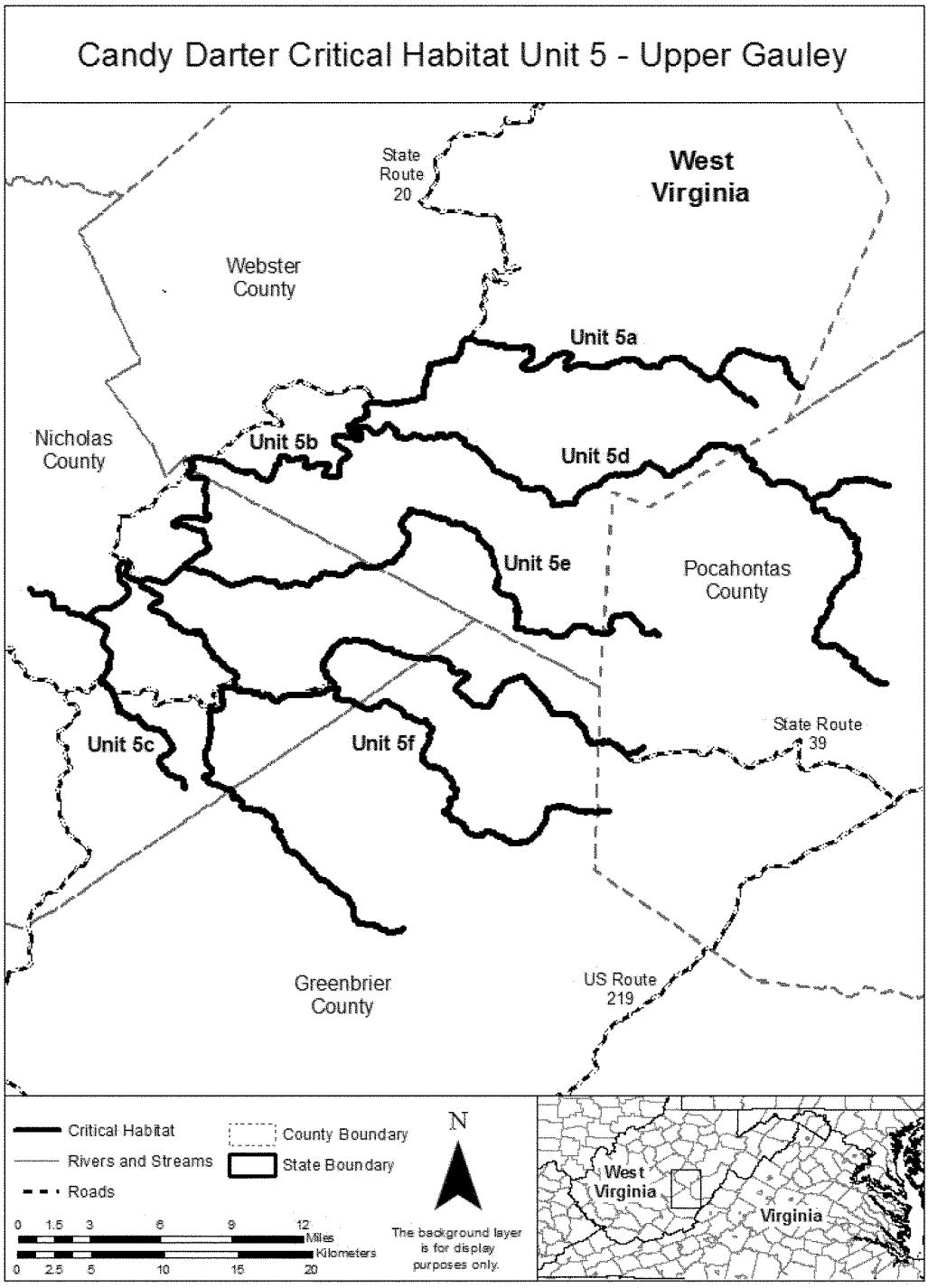
(18) Unit 4: Upper New, Cripple Creek, Wythe County, Virginia.

(i) *General description:* Unit 4 includes approximately 7.9 skm (4.9 smi) of Cripple Creek from a point approximately (2.0 smi) upstream of the State Road 94 bridge, downstream to the confluence of Cripple Creek and the New River. The stream in Unit 4 is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

(ii) Map of Unit 4, Upper New, follows:



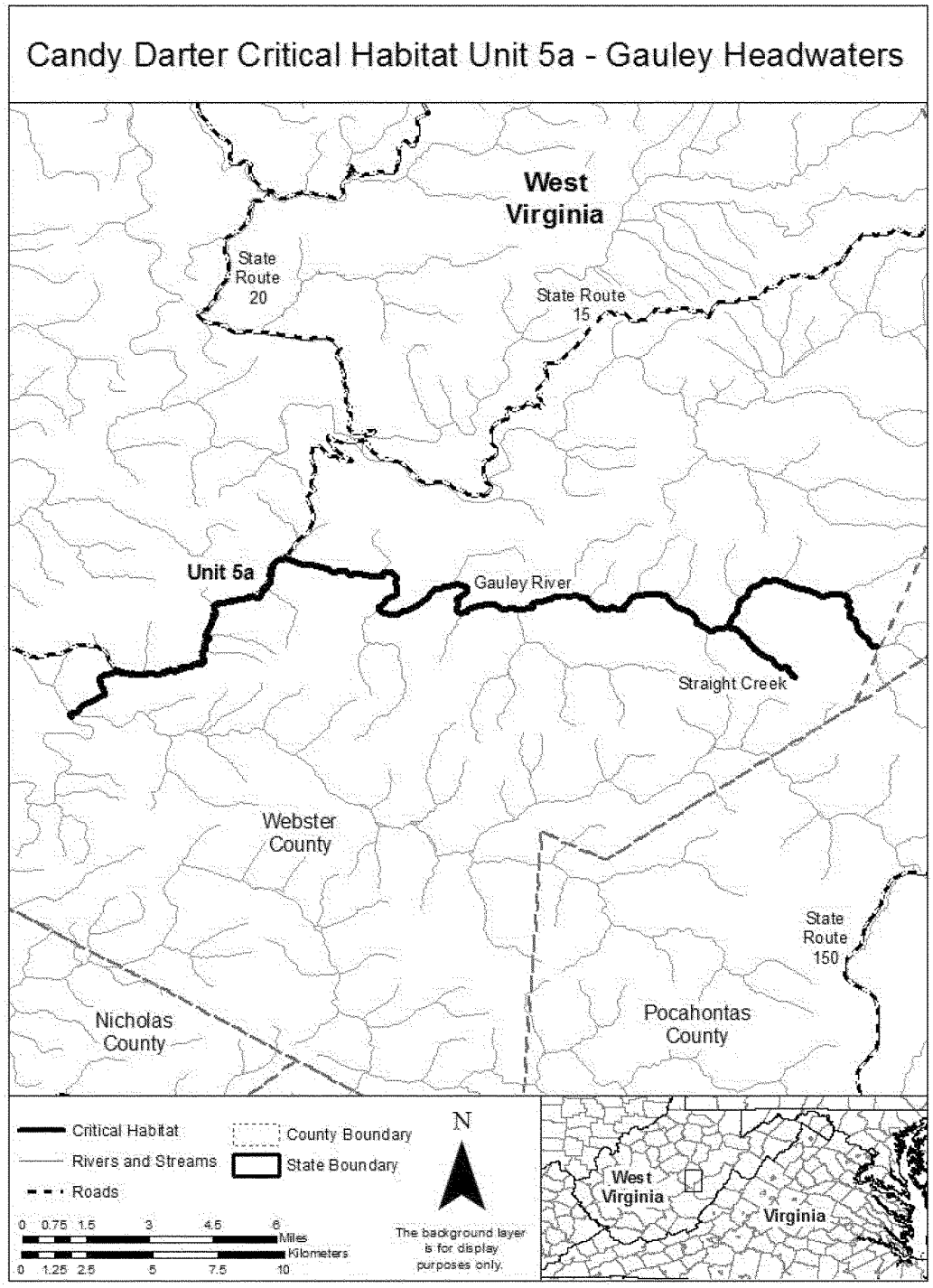
(19) Index map of Unit 5—Upper Gauley follows:



(20) Unit 5a: Gauley Headwaters, Webster County, West Virginia.

(i) *General description:* Unit 5a includes approximately 23.2 skm (37.3 smi) of the Gauley River from the North and South Forks of the Gauley River, downstream to the confluence of the Gauley River and the Williams River at Donaldson, West Virginia; and 2.9 skm (1.8 smi) of Straight Creek from its confluence with the Gauley River to a point approximately 2.9 skm (1.8 smi) upstream of the confluence. Approximately 9.0 skm (5.6 smi) of Unit 5a is within the Monongahela National Forest. The remainder of the unit is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

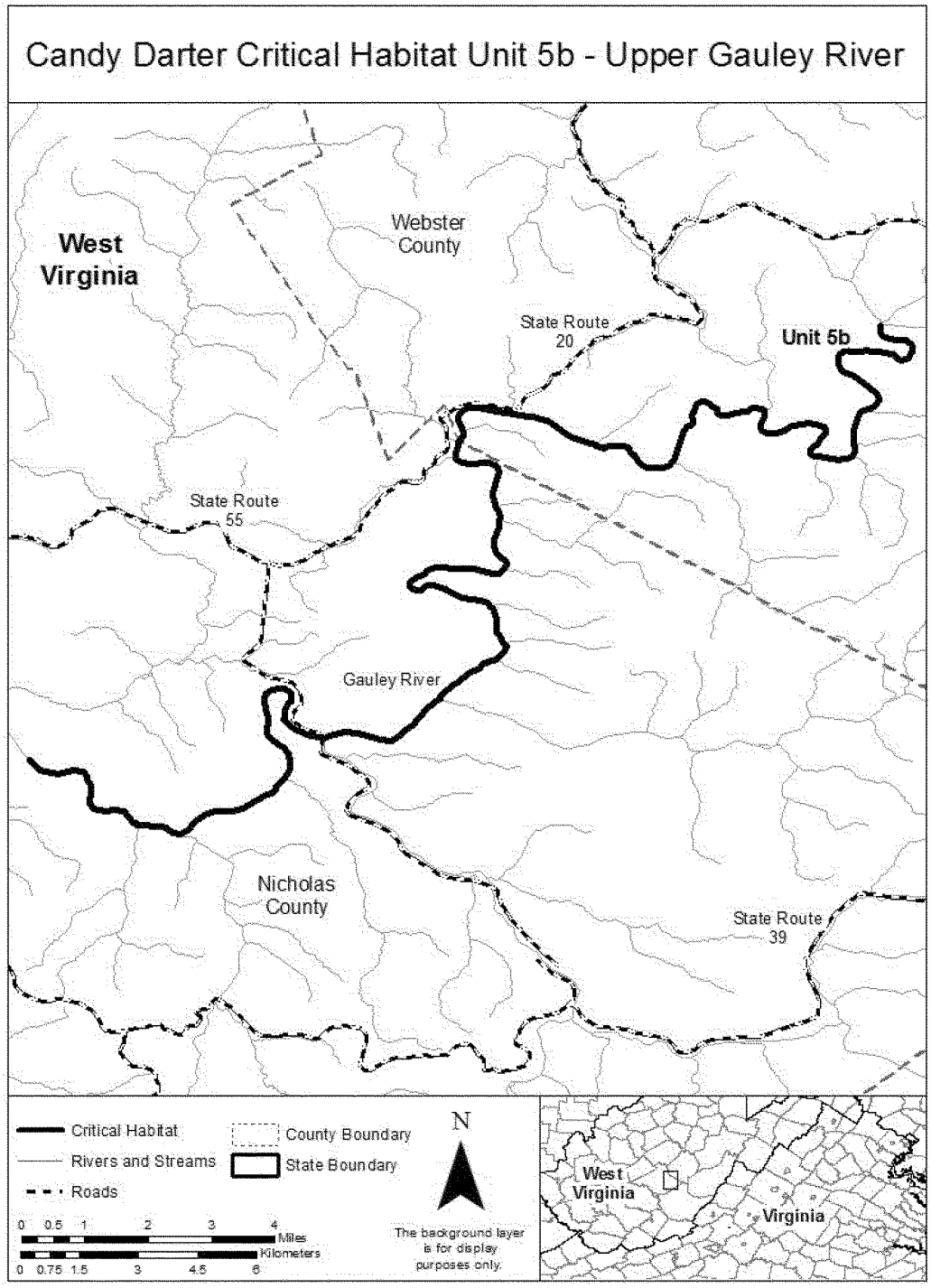
(ii) Map of Unit 5a, Gauley Headwaters, follows:



(21) Unit 5b: Upper Gauley River, Nicholas and Webster Counties, West Virginia.

(i) *General description:* Unit 5b includes approximately 43.8 skm (27.2 smi) of the Gauley River from the confluence of the Gauley and Williams Rivers at Donaldson, West Virginia, downstream to a point approximately 1.6 skm (1.0 smi) upstream of the Big Beaver Creek confluence. Approximately 14.6 skm (9.2 smi) of Unit 5b is within the Monongahela National Forest and/or adjacent to land owned by the U.S. Army Corps of Engineers. The streams in the remainder of the unit are adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

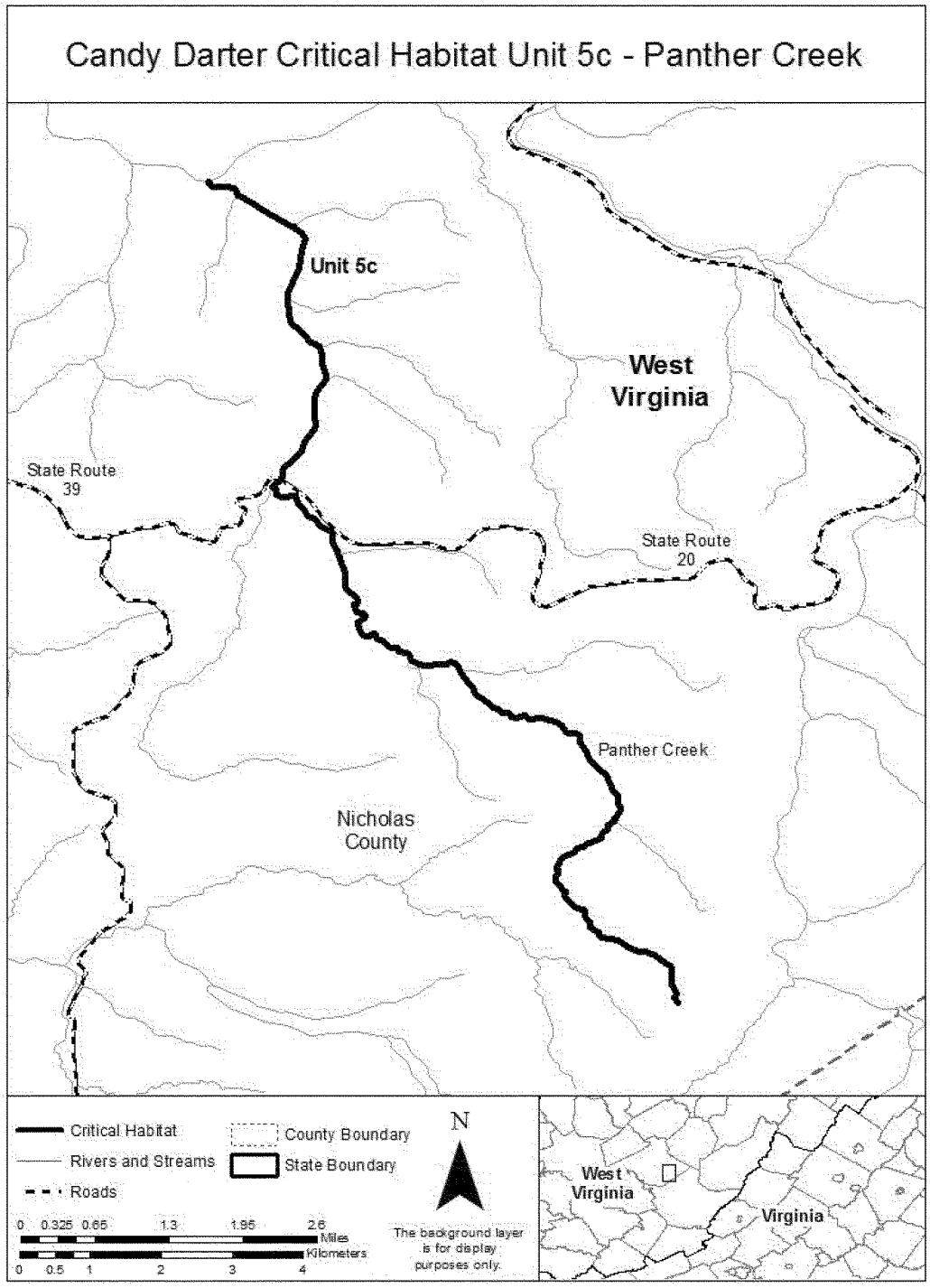
(ii) Map of Unit 5b, Upper Gauley River, follows:



(22) Unit 5c: Panther Creek, Nicholas County, West Virginia.

(i) *General description:* Unit 5c includes approximately 16.3 skm (10.1 smi) of Panther Creek from a point approximately 1.1 skm (0.7 smi) upstream of the Grassy Creek Road crossing, downstream to the confluence with the Gauley River. The streams in Unit 5c are adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

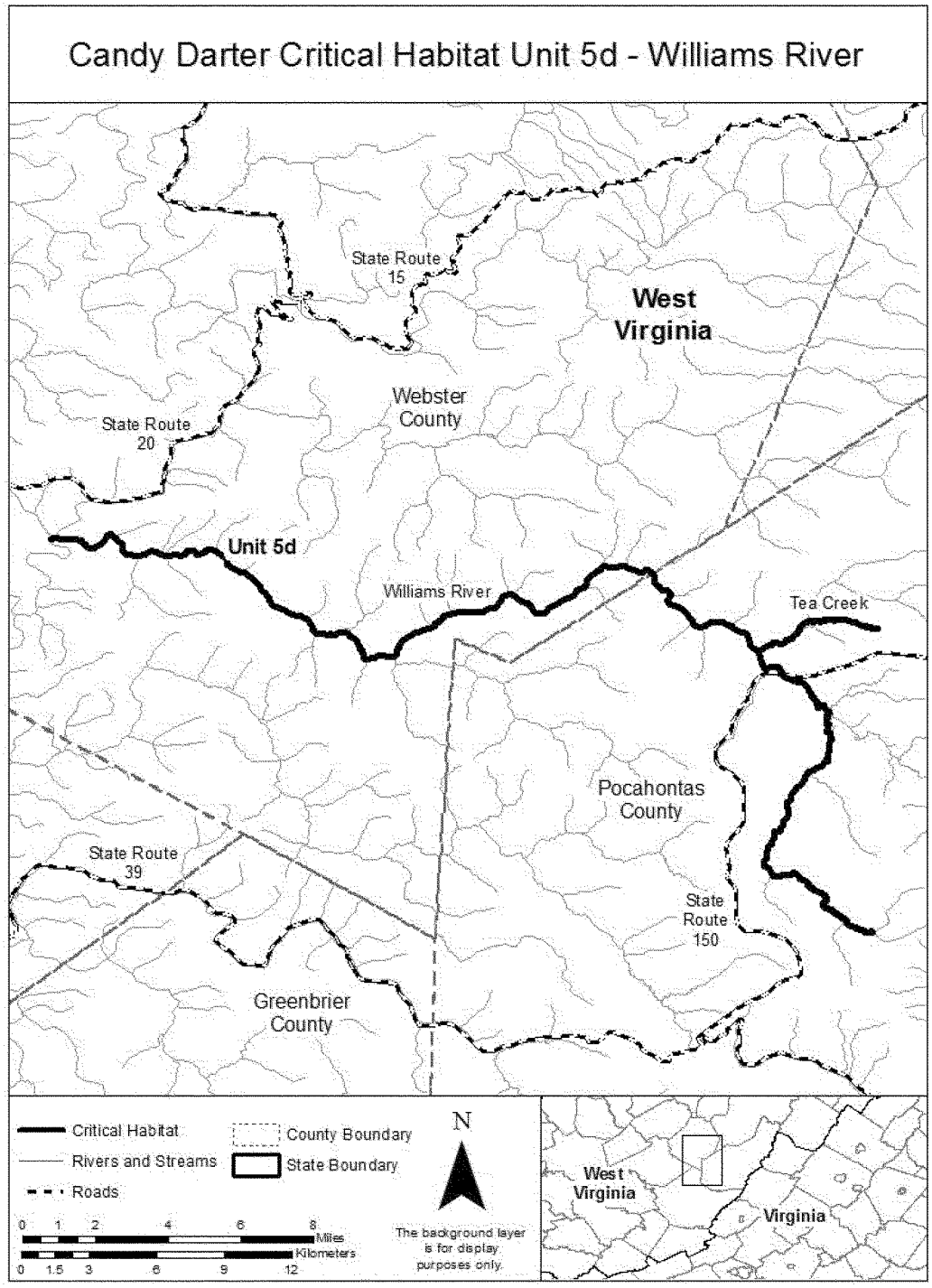
(ii) Map of Unit 5c, Panther Creek, follows:



(23) Unit 5d: Williams River, Pocahontas and Webster Counties, West Virginia.

(i) *General description:* Unit 5d includes approximately 52.4 skm (32.6 smi) of the Williams River from the confluence with Beaverdam Run, downstream to the confluence of the Williams River and the Gauley River at Donaldson, West Virginia; and 5.1 skm (3.2 smi) of Tea Creek from a point on Lick Creek approximately 2.7 skm (1.7 smi) upstream of the Lick Creek confluence, downstream to the Tea Creek confluence with the Williams River. The streams in Unit 5d are entirely within the Monongahela National Forest.

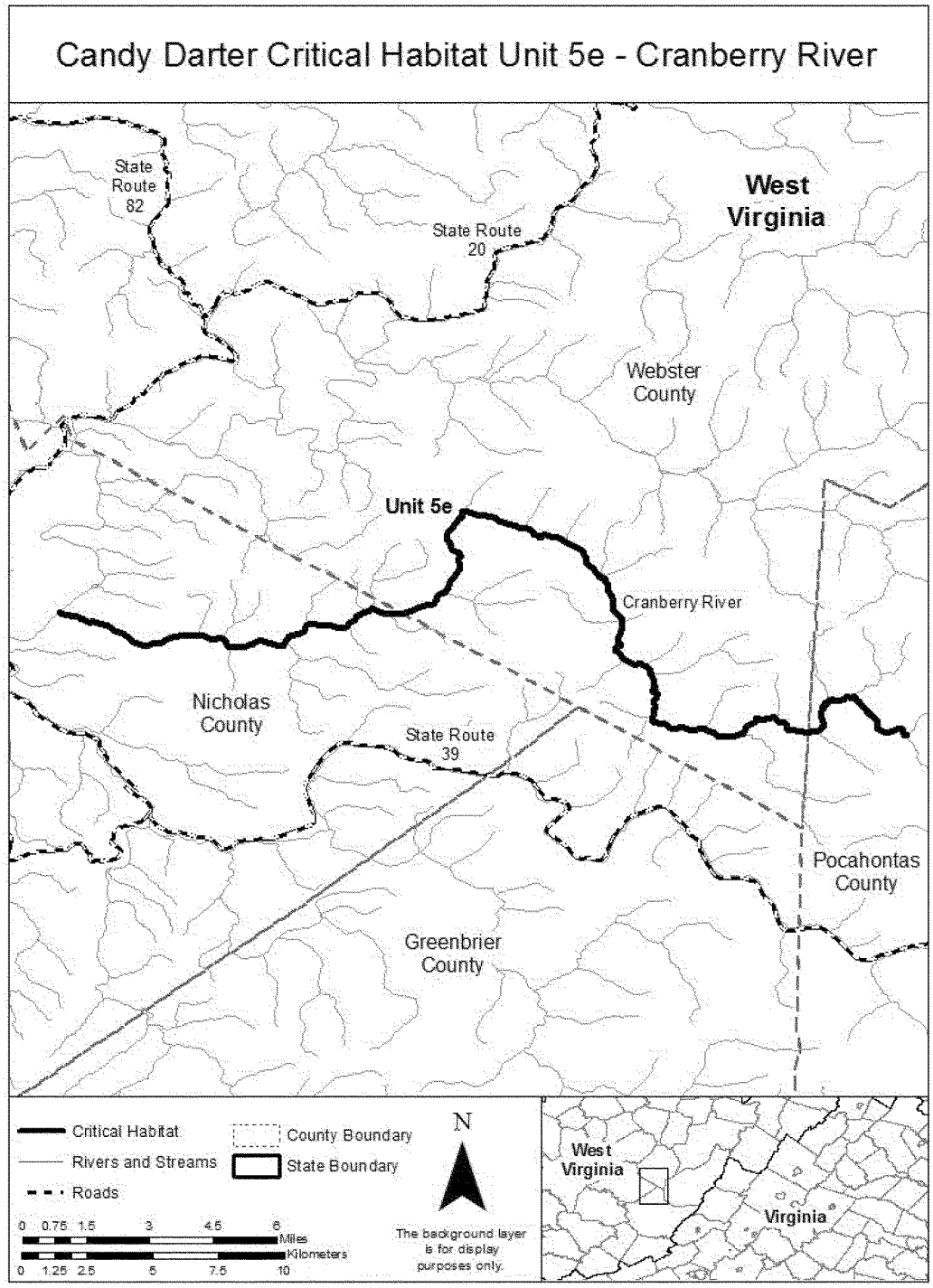
(ii) Map of Unit 5d, Williams River, follows:



(24) Unit 5e: Cranberry River, Nicholas and Webster Counties, West Virginia.

(i) *General description:* Unit 5e includes approximately 39.3 skm (24.4 smi) of the Cranberry River from the confluence of the North and South Forks of the Cranberry River, downstream to the confluence of the Cranberry River and the Gauley River. This stream is entirely within the Monongahela National Forest.

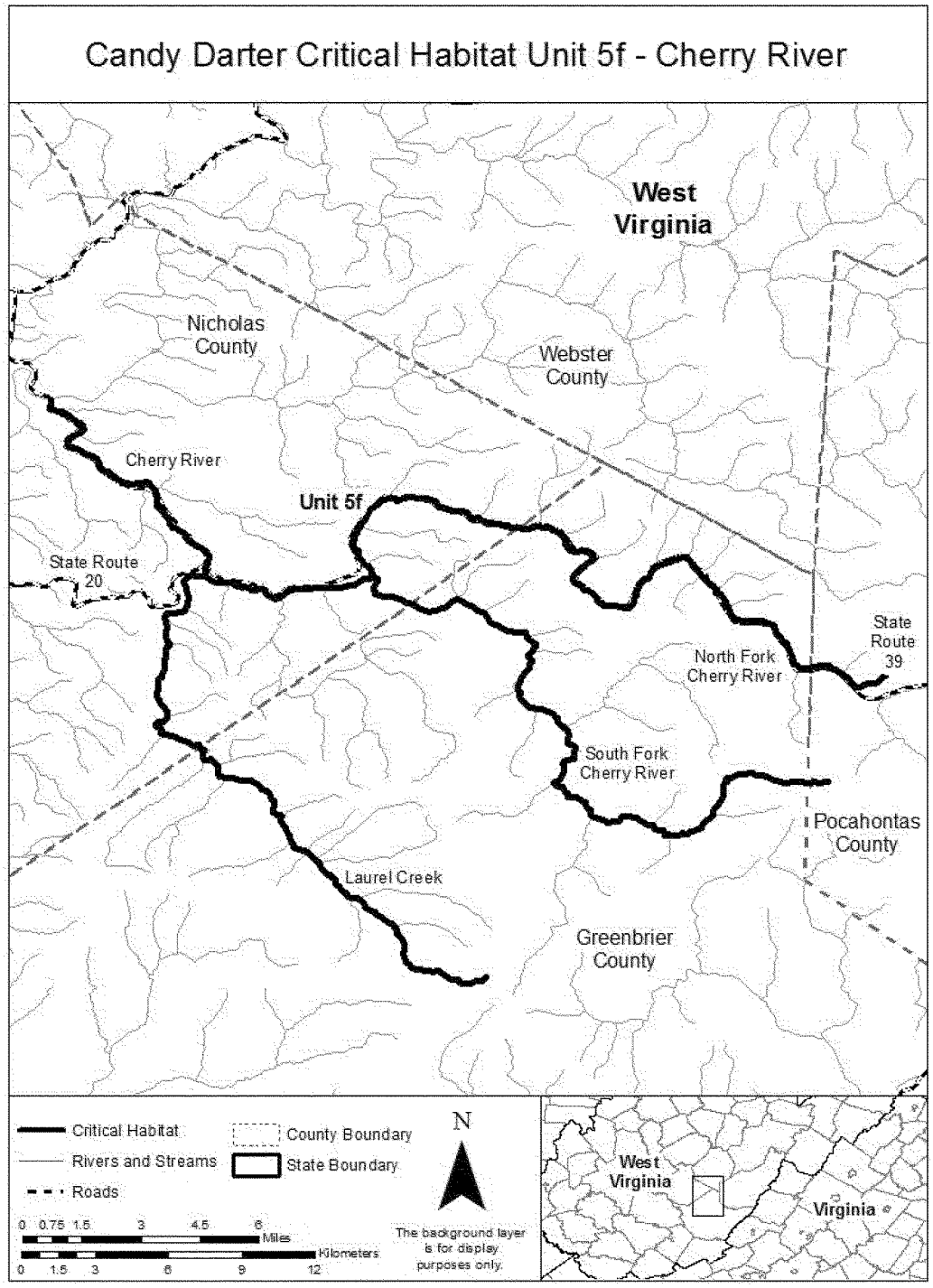
(ii) Map of Unit 5e, Cranberry River, follows:



(25) Unit 5f: Cherry River, Greenbrier and Nicholas Counties, West Virginia.

(i) *General description:* Unit 5f includes approximately 16.7 skm (10.4 smi) of Cherry River from the confluence of the North and South Forks of the Cherry River, downstream to the confluence of the Cherry River and the Gauley River; approximately 28.0 skm (17.4 smi) of the North Fork Cherry River from the Pocahontas Trail crossing, downstream to the confluence of the North and South Forks of the Cherry River; approximately 26.2 skm (16.3 smi) of the South Fork Cherry River from a point approximately 0.5 skm (0.3 smi) south of County Road 29/4 in Virginia, downstream to the confluence of the North and South Forks of the Cherry River; and approximately 24.9 skm (15.5 smi) of Laurel Creek from a point approximately 0.3 skm (0.2 smi) west of Cold Knob Road, downstream to the confluence of Laurel Creek the Cherry River. Approximately 29.1 skm (18.1 smi) of Unit 5f is within the Monongahela National Forest. The remainder is adjacent to almost entirely private land, except for a small amount that is publicly owned in the form of bridge crossings, road easements, and the like.

(ii) Map of Unit 5f, Cherry River, follows:



* * * * *

Dated: August 14, 2018.

James W. Kurth

Deputy Director, U.S. Fish and Wildlife Service, Exercising the Authority of the Director, U.S. Fish and Wildlife Service.

Note: This document was received for publication by the Office of Federal Register on November 15, 2018.

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